

1 UNITED STATES DISTRICT COURT  
2 FOR THE NORTHERN DISTRICT OF OHIO  
3 EASTERN DIVISION

4 IN RE: NATIONAL )  
5 PRESCRIPTION ) MDL No. 2804  
6 OPIATE LITIGATION )  
7 Case No.  
8 ) 1:17-MD-2804  
9 )  
10 THIS DOCUMENT RELATES ) Hon. Dan A.  
11 TO ALL CASES ) Polster  
12 )

13 FRIDAY, NOVEMBER 16, 2018

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER  
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of James  
18 Rausch, held at the offices of STINSON  
19 LEONARD STREET LLP, 7700 Forsyth Boulevard,  
20 Suite 1000, St. Louis, Missouri, commencing  
21 at 9:00 a.m., on the above date, before  
22 Carrie A. Campbell, Registered Diplomat  
23 Reporter and Certified Realtime Reporter.

24 - - -

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3 In-house Counsel for Mallinckrodt  
4 Pharmaceuticals  
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6 VIDEOGRAPHER:  
7 JAMES ARNDT,  
8 Golkow Litigation Services  
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<p>1 Mallinckrodt E-mail(s), 286 Rausch 14 MNK-T1_0000266735 - 2 MNK-T1_0000266736 3 Mallinckrodt E-mail(s), 291 Rausch 15 MNK-T1_0000266730 4 5 Mallinckrodt E-mail(s), 293 Rausch 16 MNK-T1_0000298447 6 Mallinckrodt E-mail(s), 298 Rausch 17 MNK-T1_0000387257 - 7 MNK-T1_0000387258 8 (Exhibits attached to the deposition.) 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 MR. TILLY: Jason Tilly, 2 Mallinckrodt Pharmaceuticals. 3 MS. CONWAY: Sarah Conway on 4 behalf of Walmart. 5 MS. HERZFELD: Tricia Herzfeld 6 on behalf of plaintiffs for the 7 Tennessee state litigation. 8 VIDEOGRAPHER: The court 9 reporter is Carrie Campbell, and she 10 will now swear in the witness. 11 MR. YINGLING: Yeah, this is 12 Patrick Yingling for 13 AmerisourceBergen. 14 MR. PERSKIE: Jacob Perskie 15 from Fox Rothschild for Validus 16 Pharmaceuticals in the Arkansas 17 matter. 18 MS. YOCUM: Michelle Yocum from 19 on behalf of McKesson. 20 MS. MCNAMARA: Colleen McNamara 21 on behalf of Cardinal Health. 22 MR. RICARD: Paul Ricard on 23 behalf of Prescription Supply, Inc. 24 25</p>

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1 JAMES RAUSCH,  
2 of lawful age, having been first duly sworn  
3 to tell the truth, the whole truth and  
4 nothing but the truth, deposes and says on  
5 behalf of the Plaintiffs, as follows:  
6  
7 DIRECT EXAMINATION  
8 QUESTIONS BY MR. KAWAMOTO:  
9 Q. Good morning, Mr. Rausch.  
10 A. Good morning.  
11 Q. Thank you for being here today.  
12 So my name is Dean, and my  
13 colleagues are Gary and Erika.  
14 I'm going to plan to take a  
15 break probably around every hour, but if you  
16 need one earlier, just please let me know.  
17 A. Okay.  
18 Q. Could you please state your  
19 name and business address?  
20 A. James Rausch, and I'm currently  
21 retired.  
22 Q. And you understand that you're  
23 under oath, right, sir?  
24 A. Yes.  
25 Q. And are you taking any

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1 medications, or is there any other reason  
2 that would interfere with your ability to  
3 answer my questions fully and truthfully?  
4 A. I'm taking medications, but it  
5 wouldn't interfere with being able to answer  
6 the questions.  
7 Q. Thank you.  
8 And if I ask a question you  
9 don't understand, please let me know and I  
10 will try to rephrase it.  
11 A. Okay.  
12 Q. Have you ever testified in a  
13 deposition?  
14 A. No.  
15 Q. Okay. So some basic ground  
16 rules, just primarily for the benefit of the  
17 court reporter, but it's very important that  
18 when I ask you a question, that you answer  
19 verbally as opposed to nodding or shaking  
20 your head.  
21 A. Okay.  
22 Q. And it's also very important  
23 that we not speak over each other. So I'll  
24 ask my question, and then I'll let you  
25 answer.

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1 Your attorney may object for  
2 the record. Unless he instructs you not to  
3 answer, though, you are to answer the  
4 question.  
5 A. Okay.  
6 Q. Have you ever testified at  
7 trial?  
8 A. One -- once.  
9 Q. And can you describe the --  
10 well, what was the nature of that trial?  
11 A. Someone stole firearms from my  
12 house -- or my apartment at the time. I went  
13 to testify on identifying the firearm.  
14 Q. And who are the other people  
15 seated next to you today?  
16 A. These are the lawyers  
17 representing Mallinckrodt.  
18 Q. And are they also your  
19 attorneys?  
20 A. They represent me.  
21 Q. Okay. And are you paying them  
22 to be here today?  
23 A. No.  
24 Q. Okay. Do you know who is  
25 paying them?

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1 A. Mallinckrodt.  
2 Q. So, sir, I want to ask you a  
3 few questions about your deposition  
4 preparation.  
5 Did you review any documents in  
6 preparation for this deposition?  
7 A. That's attorney-client  
8 privilege.  
9 Q. My understanding, and Rocky can  
10 object if he feels he needs to, but I'm not  
11 asking you to identify for me the documents  
12 that you reviewed. I just want to know if  
13 you reviewed any documents.  
14 MR. TSAI: You can answer that  
15 question.  
16 THE WITNESS: Yes.  
17 QUESTIONS BY MR. KAWAMOTO:  
18 Q. Okay. And did you review any  
19 deposition transcripts or other trial  
20 testimony?  
21 A. No.  
22 Q. And did you review any expert  
23 reports?  
24 A. Excerpt reports?  
25 Q. Expert reports.

<p style="text-align: right;">Page 14</p> <p>1 A. No.</p> <p>2 Q. My apologies.</p> <p>3 Do you recall reviewing any</p> <p>4 court documents?</p> <p>5 A. No.</p> <p>6 Q. And what about any electronic</p> <p>7 records, for example, any databases?</p> <p>8 A. No.</p> <p>9 Q. Now, have you looked at your</p> <p>10 own personal paper or electronic files to</p> <p>11 prepare for this deposition?</p> <p>12 A. No, I've been retired for</p> <p>13 almost six years.</p> <p>14 Q. Now, I take it you spoke with</p> <p>15 your attorneys prior to this deposition; is</p> <p>16 that fair?</p> <p>17 A. Yes.</p> <p>18 Q. And do you recall whether it</p> <p>19 was in person or by phone or both?</p> <p>20 A. In person.</p> <p>21 Q. And on how many occasions did</p> <p>22 you speak with them?</p> <p>23 A. Three times.</p> <p>24 Q. And do you recall roughly how</p> <p>25 many hours on each occasion it was?</p>	<p style="text-align: right;">Page 16</p> <p>1 ask you to identify those -- I will</p> <p>2 ask you to identify those documents.</p> <p>3 Rocky?</p> <p>4 MR. TSAI: I object on</p> <p>5 attorney-client privilege and work</p> <p>6 product grounds, and I instruct the</p> <p>7 witness not to answer to the extent</p> <p>8 the question is asking him to identify</p> <p>9 documents that were selected and</p> <p>10 compiled by counsel and discussed with</p> <p>11 counsel.</p> <p>12 QUESTIONS BY MR. KAWAMOTO:</p> <p>13 Q. Okay. So I'm going to try to</p> <p>14 modify that question, and your attorney may</p> <p>15 also have the same objection.</p> <p>16 But can you generally describe</p> <p>17 for me the categories of documents that you</p> <p>18 looked at to refresh your recollection?</p> <p>19 A. I believe that's</p> <p>20 attorney-client privilege.</p> <p>21 E-mails, I guess, would be the</p> <p>22 answer to that.</p> <p>23 Q. And other than your attorneys,</p> <p>24 did you speak to anyone else to prepare for</p> <p>25 your deposition?</p>
<p style="text-align: right;">Page 15</p> <p>1 A. Four or five hours, roughly.</p> <p>2 Q. And this is four or five hours</p> <p>3 each time?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And at these meetings,</p> <p>6 who was present?</p> <p>7 A. Rocky and Bill.</p> <p>8 Q. And so no one else was present</p> <p>9 other than --</p> <p>10 A. No.</p> <p>11 Q. -- Rocky and Bill?</p> <p>12 Now, you indicated that you</p> <p>13 reviewed documents.</p> <p>14 Did any of those documents</p> <p>15 refresh your recollection regarding the</p> <p>16 issues at this deposition?</p> <p>17 A. Yes. Considering that I've</p> <p>18 been retired for six years, so I had not seen</p> <p>19 any of these documents for quite a long time.</p> <p>20 MR. KAWAMOTO: Okay. And I</p> <p>21 take it, Mr. Tsai, if I ask him to</p> <p>22 identify those documents, you'll</p> <p>23 object on privilege?</p> <p>24 MR. TSAI: Yes.</p> <p>25 MR. KAWAMOTO: Okay. So I will</p>	<p style="text-align: right;">Page 17</p> <p>1 A. No, sir.</p> <p>2 Q. Okay. Now, sir, are you being</p> <p>3 reimbursed by anyone for your expenses in</p> <p>4 connection with this deposition?</p> <p>5 A. No, sir.</p> <p>6 Q. And so Mallinckrodt is not</p> <p>7 compensating you for your time in connection</p> <p>8 with this deposition?</p> <p>9 A. No, sir.</p> <p>10 Q. Can you brief -- strike that.</p> <p>11 Can you briefly describe your</p> <p>12 education background after high school?</p> <p>13 A. I went to college for three</p> <p>14 years in pursuit of a major in psychology,</p> <p>15 and -- I was hired -- this was in '76, I was</p> <p>16 hired as -- at Mallinckrodt as a summer</p> <p>17 replacement for people going on vacation, and</p> <p>18 I ended up staying on full time, so I never</p> <p>19 did finish school.</p> <p>20 Q. And roughly when you did you</p> <p>21 start working at Mallinckrodt?</p> <p>22 A. 1976.</p> <p>23 Q. And you say you retired six</p> <p>24 years ago. So forgive my math, but that</p> <p>25 would be 2012?</p>



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1 A. 2013. January.  
 2 Q. Okay. And so between 1976 and  
 3 2013, you were employed by Mallinckrodt?  
 4 A. That's correct.  
 5 Q. And so you've never worked for  
 6 anyone else other than Mallinckrodt?  
 7 A. Correct.  
 8 Q. Have you completed any  
 9 nondegree programs of study?  
 10 And if you don't understand  
 11 what that means, I'm happy to clarify.  
 12 A. Would you clarify that?  
 13 Q. Have you taken any other  
 14 courses or any training outside of  
 15 Mallinckrodt, for example, any -- do you have  
 16 any regulatory certifications or professional  
 17 licenses?  
 18 A. No.  
 19 Q. So I would like to ask you  
 20 about your employment at Mallinckrodt, and  
 21 recognizing that it covers 1976 to 2013, it's  
 22 a broad time period, so I'll understand if  
 23 you don't remember the details, particularly  
 24 from the earlier time.  
 25 But can you generally walk me

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1 through the different positions that you've  
 2 held since starting at Mallinckrodt?  
 3 A. Sure, I'll try.  
 4 As I said, in 1976 I was hired  
 5 as a replacement for -- in customer service.  
 6 It was a business that no longer is with  
 7 Mallinckrodt.  
 8 And I eventually was hired full  
 9 time, and after about a year, that business  
 10 moved to Paris, Kentucky, and I stayed in  
 11 St. Louis and got a position in the  
 12 production and inventory control area in our  
 13 bulk business.  
 14 Q. Okay. And if I could pause you  
 15 there.  
 16 So when were you hired full  
 17 time, roughly what year?  
 18 A. It was in '76.  
 19 Q. And you were initially hired  
 20 into customer service for a business that  
 21 subsequently moved?  
 22 A. Right.  
 23 Q. A business line that  
 24 subsequently moved?  
 25 A. Right.

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1 Q. And then when did you go to  
 2 production and inventory, roughly what year?  
 3 A. I would say '77.  
 4 Q. Okay. And I'm sorry, go ahead.  
 5 You were saying something about, I think it  
 6 was a bulk business?  
 7 A. Yes, the bulk business that  
 8 Mallinckrodt had there. I was a production  
 9 and inventory control planner.  
 10 Q. And what did that entail? I'm  
 11 not familiar with that term.  
 12 A. It entailed planning the  
 13 production of inventory for material that was  
 14 to be sold. Based upon inventory levels, we  
 15 would -- we would plan the raw materials that  
 16 needed to be brought in and then the  
 17 production schedules for the production of  
 18 the material.  
 19 Q. And so you're talking about raw  
 20 materials that would be, I guess, turned into  
 21 pharmaceuticals?  
 22 A. This is not pharmaceuticals at  
 23 that time. I was not in the  
 24 pharmaceutical -- I was in the specialty  
 25 chemical business, which was for raw

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1 materials that went into food -- food --  
 2 foods and industrial applications. This was  
 3 all down in our St. Louis plant. And this  
 4 was a raw material; it was not a finished  
 5 good.  
 6 Q. And so is it fair to say that  
 7 your job was to make sure that you had  
 8 sufficient amounts of the raw materials to  
 9 make the needed amounts of the finished  
 10 goods?  
 11 A. That was part of it, yes, to  
 12 make sure that the raw materials were  
 13 scheduled to be brought in on time so when we  
 14 were scheduling the run for making the  
 15 product that we wanted to make was there in  
 16 time.  
 17 Q. Okay. And how long did you  
 18 continue with those responsibilities?  
 19 A. I did that from  
 20 approximately -- well, I was a planner for  
 21 several years, and then I became a supervisor  
 22 over four or five planners, and I was in that  
 23 position until '91, and then I went to work  
 24 in customer service as a manager.  
 25 Q. And was that still related to

<p style="text-align: right;">Page 22</p> <p>1 raw chemicals in -- or was that in 2 pharmaceuticals? 3 A. Yes, still -- I had the 4 acetaminophen, our acetaminophen customer 5 service group, I had our specialty chemical 6 group, and our bulk narcotic group reporting 7 to me. 8 Q. Okay. 9 A. And I reported into the sales 10 for the -- for the bulk area. 11 Q. And what is -- what is the 12 specialty chemical group? 13 A. Well, like I said, the 14 specialty chemical group is for raw materials 15 for us to produce finished good, raw 16 materials for, say, food applications. We 17 sold raw materials to Anheuser Busch. We 18 sold industrial chemicals, but they were all 19 raw material and then they would further take 20 our raw material and combine it with their 21 raw materials to make finished good or 22 whatever application they were using it for. 23 Q. And none of these raw materials 24 related to the manufacture of opioids; is 25 that fair?</p>	<p style="text-align: right;">Page 24</p> <p>1 continued to be a raw material. That was 2 considered our finished good. 3 Q. Okay. 4 A. And was sold in bulk 5 quantities, hundred -- hundred kilos or 6 hundred pounds at a time. 7 Q. So I just want to make sure 8 that I've got the timing correct. 9 So in '91 you became a manager 10 and -- you became a manager of the 11 acetaminophen customer service group, the 12 specialty chemical group and the bulk 13 narcotic group; is that correct? 14 A. That's correct. 15 Q. And did you -- did you later go 16 on other positions, or did you stay in that 17 position? 18 A. Yes, I had that position until 19 approximately the fall of 2008, and then I 20 took over customer service for the dosage 21 business. 22 Q. And can you describe for me 23 what the dosage business is? 24 A. The dosage business is when you 25 take raw material products, opiate products,</p>
<p style="text-align: right;">Page 23</p> <p>1 A. That was another group. That 2 was our -- that was our bulk narcotic group. 3 Q. Okay. And what -- can you 4 define for me, what is a bulk -- or what is a 5 bulk narcotic group? 6 A. A bulk narcotic is a -- a raw 7 material that we produce from opiate and the 8 raw material is then sold to another 9 manufacturer who adds chemical -- other 10 chemicals to that -- our raw material to make 11 a finished product. Pills, powder, tablets. 12 We did not make a finished 13 good, product, in the bulk area. 14 Q. And the pills and powders and 15 tablets, that would later be sold to, for 16 example, distributors? 17 A. Yes, from the manufacturers 18 that we sold to. 19 Q. And when you say that you did 20 not make a finished good or a product, that's 21 with respect to the bulk narcotics; is that 22 correct? 23 A. Correct. And when I say 24 "finished good," in your terms, it was not in 25 a tablet form or whatever. It was a --</p>	<p style="text-align: right;">Page 25</p> <p>1 and combine them with other chemicals to make 2 a finished good in the tablet or powder form. 3 Q. So when you say you take raw 4 material products, this was Mallinckrodt raw 5 material products and making them into opioid 6 products? 7 A. Yes. 8 Q. And these opioid products would 9 subsequently be shipped out to Mallinckrodt's 10 customers; is that correct? 11 A. Yes. Our distributor customers 12 and that, yes. 13 Q. And you held this position from 14 2008 until you retired in 2012 -- or I'm 15 sorry, 2013? 16 A. Correct. 17 Q. Who was your predecessor in 18 this position -- I'm sorry, in this position? 19 A. Cathy Stewart. 20 Q. I know if I -- if I could go 21 back to the -- the bulk narcotics business 22 for a second. 23 A. Yes. 24 Q. Do you recall who the 25 manufacturers were who purchased bulk</p>

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1 narcotics from Mallinckrodt?  
 2 A. Oh, gosh. Purdue was one of  
 3 the bigger ones. I don't remember -- I don't  
 4 remember all of them.  
 5 Q. Well, do you recall if Endo  
 6 purchased any?  
 7 A. Endo, I believe, was one of  
 8 them, yes.  
 9 Q. Okay. What about Teva?  
 10 A. Yes.  
 11 Q. What about Allergan?  
 12 A. I believe so.  
 13 Q. Okay. How about Johnson &  
 14 Johnson?  
 15 A. Yes.  
 16 Q. How about Janssen?  
 17 A. I believe so.  
 18 Q. So in the context of the bulk  
 19 narcotics business, you sold to most of the  
 20 major manufacturers in the market; is that  
 21 fair?  
 22 A. Yes.  
 23 Q. Sir, was your retirement  
 24 voluntary?  
 25 A. Yes.

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1 Q. So you could have stayed on if  
 2 you wanted to; you just decided it was time  
 3 to go?  
 4 A. Yes.  
 5 Q. And can you briefly -- well,  
 6 strike that.  
 7 The position you held from fall  
 8 of 2008 until 2013, what was your title?  
 9 A. Manager of customer service.  
 10 Q. And it was manager of customer  
 11 service for dosage products, is that the  
 12 full --  
 13 A. Yes.  
 14 Q. And what was your compen --  
 15 well, what was your compensation scheme for  
 16 your -- for your position?  
 17 In other words, were you paid a  
 18 base? Did you also have a bonus? How was  
 19 that determined?  
 20 A. At the time I reported into the  
 21 logistics group, which included customer  
 22 service, shipping and warehousing, and we did  
 23 have a bonus that was based upon backorders,  
 24 how long it took us to -- to answer the  
 25 phone, that type of thing. Very

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1 customer-service-based compensation.  
 2 Q. So do you recall in -- for  
 3 2012, what was your base compensation?  
 4 A. As far as dollars?  
 5 Q. Yes.  
 6 A. I don't remember.  
 7 Q. And do you recall what your  
 8 bonus was?  
 9 A. Oh, my base as far as salary?  
 10 Q. Yes, your base salary.  
 11 A. It was probably around 90,000.  
 12 Q. And then do you recall what  
 13 your bonus was for that year?  
 14 A. No. But it was like 10 percent  
 15 was the -- was the most I could make, if I  
 16 met my objectives.  
 17 MR. TSAI: And, Dean, I know  
 18 that the depo transcripts are  
 19 presumptively highly confidential, but  
 20 because you're getting into personal  
 21 financial information, I do want to  
 22 designate this discussion as highly  
 23 confidential.  
 24 MR. KAWAMOTO: Sure, that's  
 25 fine.

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1 QUESTIONS BY MR. KAWAMOTO:  
 2 Q. And the \$90,000, was this --  
 3 was this more or less your base salary for  
 4 the 2008 to 2013 time period?  
 5 A. Well, we had yearly reviews,  
 6 and based upon reviews and if you met your  
 7 goals and that type of thing, depending on  
 8 what the percentage was for that year, you  
 9 know, it could go up or stay the same.  
 10 Q. And were your reviews generally  
 11 positive in your opinion?  
 12 A. Yes. Yes.  
 13 Q. Did anyone ever express any  
 14 concerns about your performance?  
 15 A. No.  
 16 Q. And in terms of your goals,  
 17 what are the goals that you recall that you  
 18 were evaluated based on?  
 19 A. I don't remember many of them.  
 20 It's been a long time. But again, like I  
 21 said, it was based upon, say, call answering  
 22 rate, we needed to have it above 95 percent,  
 23 so we would keep track of that, and that  
 24 would be one goal.  
 25 Keeping our backorders down to,



<p style="text-align: right;">Page 30</p> <p>1 I forget what percentage, was another goal.  2 We had other goals as far as  3 having the CSRs attend -- or sign up for  4 different seminars, and we were responsible  5 for making sure that they met their goals  6 there. So that was another thing that we  7 were graded on.  8 Just a few that I can think of.  9 Q. Were any of these goals  10 compliance related?  11 A. Karen Harper would have yearly,  12 if I remember right, a review of what was  13 going on in compliance and kind of keep us  14 abreast of any -- any new regulations or  15 anything like that that we may need to know  16 about.  17 Q. And so was your compensation  18 based, in part, on your ability to comply  19 with these regulations?  20 A. No.  21 Q. And who reported to you?  22 You were a manager, so who were  23 the people under you?  24 A. I had five CSRs and one being a  25 lead.</p>	<p style="text-align: right;">Page 32</p> <p>1 there wasn't many because the DEA wanted to  2 keep control of where the production -- how  3 much production was being put out and who was  4 producing it.  5 Q. So would you describe yourself  6 as one -- as essentially the dominant player  7 in the bulk narcotics business?  8 A. I would say we were --  9 MR. TSAI: Object to the form.  10 Go ahead.  11 THE WITNESS: -- we were one of  12 the larger producers.  13 QUESTIONS BY MR. KAWAMOTO:  14 Q. And who were the other larger  15 producers in that space?  16 A. Like I said, I don't remember.  17 Q. Would you -- do you believe you  18 were the largest producer in that space?  19 MR. TSAI: Objection. Vague as  20 to time.  21 THE WITNESS: Yes, it depends  22 on the time frame that we're speaking.  23 Early on we were probably one  24 of the largest ones. I'm not saying  25 we were the largest or not, I don't</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. Okay. And do you recall their  2 names?  3 A. No, not all of them. Brenda  4 Raycop was the lead. I don't remember the  5 rest of their names.  6 Q. And who did you report to?  7 A. Well, at one time it was  8 Michael Phenev and George -- last one was  9 George -- I forget his last name now.  10 Q. Is it George Saffold?  11 A. Saffold, yes.  12 Q. And you mentioned Karen Harper.  13 A. Yes.  14 Q. Did you report to her?  15 A. No.  16 Q. So going back to the bulk  17 narcotics business.  18 Who would you say were your  19 main competitors in that field?  20 A. Back then, we didn't have a  21 whole lot of competitors within the United  22 States. We had a -- we had a sizeable  23 percentage of the -- of the production that  24 the DEA allowed within the country. I don't  25 remember who they were, but it wasn't --</p>	<p style="text-align: right;">Page 33</p> <p>1 remember, but we were in the top  2 three, I would say.  3 QUESTIONS BY MR. KAWAMOTO:  4 Q. So, no, I understand that there  5 are limits to your memory.  6 A. Right.  7 Q. So what was the time frame  8 where you would -- where it would be fair to  9 say you were probably one of the largest?  10 A. Well, like I said, I don't  11 remember.  12 Q. Roughly would this be in the  13 2000s? In the '90s?  14 A. Roughly, probably in the '90s  15 and early 2000.  16 Q. And then I guess when you say  17 early 2000s, are we talking like 2005 to  18 2000 -- I'm sorry, 2000 to 2005 or 2006?  19 A. 2000 to 2005 would be -- from  20 what I remember.  21 Q. And then after 2005, you were  22 still a large producer; you just weren't the  23 largest; is that fair?  24 A. That's true.  25 Q. Now, focusing on your position</p>

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1 from 2008 to 2013, which is when you were the  
2 customer service manager for dosage products.

3 A. Okay.

4 Q. What training did you receive  
5 for your -- for that position?

6 A. Training was mostly done by the  
7 previous customer service rep or manager,  
8 Cathy Stewart.

9 Q. And do you recall what she did  
10 to train you?

11 A. We just went over the processes  
12 that the CSRs and that had to -- what was  
13 needed as far as orders, forms needed from  
14 the customers before we could ship orders  
15 out, who their customers were, the product  
16 line, that type of thing.

17 Q. And when you say "who their  
18 customers were," were you -- are you  
19 referring to Mallinckrodt's direct customers  
20 or the customers of your customer?

21 A. Mallinckrodt's direct  
22 customers.

23 Q. And when you say "product  
24 line," what are you referring to?

25 A. This -- the products that we

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1 sold in the finished good form. We're  
2 talking about hydrocodone, oxycodone,  
3 codeine, those type of products.

4 Q. And are you referring to  
5 Mallinckrodt's generic products?

6 A. Yes.

7 Q. Okay. Would the product lines  
8 you're responsible for also include  
9 Mallinckrodt's branded products?

10 A. Yes.

11 Q. Now, are you familiar with the  
12 term "suspicious order monitoring"?

13 A. Yes, I am.

14 Q. What does that term mean to  
15 you?

16 A. It was a process -- well,  
17 depends on what time frame we're talking  
18 about. When I was in the bulk business as a  
19 customer service manager, when we first  
20 developed the suspicious order monitoring  
21 program requested by our St. Louis DEA, it  
22 was a monthly report that we sent to them  
23 showing orders that were out of the ordinary  
24 as far as quantity or frequency, that type of  
25 a report. It was sent to our DEA field

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1 office on a monthly basis.

2 Q. I'm sorry.

3 And roughly what time frame was  
4 this process in effect for?

5 A. Probably 2000 -- and I'm  
6 guessing because I don't remember exactly  
7 when we started, when they requested this.

8 But I would say probably 2003,  
9 '4 to 2006 or '7.

10 Q. And I take it the process then  
11 changed in 2006 or '7?

12 A. That's -- that's correct.

13 Q. Okay. And what was that  
14 different process then?

15 A. We started working on a more  
16 enhanced suspicious order program at the  
17 request of our compliance group to automate  
18 it so we were capturing information on orders  
19 at the time of -- the order was entered. It  
20 was based upon a lot more detail than what we  
21 had previously been supplying the DEA. The  
22 DEA was in the process of changing what they  
23 wanted to see and what they wanted to see  
24 their customers, I'll call them, or the  
25 registrants, what they wanted from them, from

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1 the registrants, and it became more complex  
2 than what we had previously.

3 Q. And so I guess for simplicity's  
4 sake, I will refer to the earlier suspicious  
5 order monitoring program as the pre-2007  
6 program, and then the enhanced one is either  
7 the enhanced SOM or the post-2007; does that  
8 make sense?

9 A. That's fine.

10 Q. Okay. So for the pre-2007 SOM  
11 program, how did you identify the suspicious  
12 orders?

13 A. It was -- the system -- it was  
14 put into our order entry system and it was  
15 based upon a log rhythm {sic} that we had  
16 come up with and designed and was approved by  
17 the DEA field office based upon the average  
18 order quantity. And I believe it was 2 X was  
19 the quantity that would flag an order on our  
20 system -- 2 X meaning two times the normal  
21 order pattern that the customer placed. And  
22 it was a -- a running total. So it wasn't  
23 just based upon a year. It was based upon  
24 the previous 12 rolling months.

25 Q. And so just so I understand

<p style="text-align: right;">Page 38</p> <p>1 sort of mathematically how this works, are  2 you essentially looking at the average over  3 the past 12 months and then seeing if the new  4 order is more than two times that average?  5 A. That's correct.  6 Q. Okay. So if the average -- I  7 understand that there may be different sort  8 of metrics, but if the average I had was,  9 let's say, 50 bottles per month --  10 A. Correct.  11 Q. -- that means that my new order  12 could be, I guess, up to a hundred bottles;  13 is that fair?  14 A. Correct.  15 Q. Okay.  16 A. And keep in mind we not only  17 had the suspicious order monitoring program,  18 but the customers that we sold to also had to  19 supply quota forms and that, which was issued  20 by the DEA, on what they could buy. And 222  21 forms was another requirement giving -- that  22 had to be supplied with every order that they  23 placed.  24 Q. And are they -- when you say  25 "quota forms," is that the same as the 222</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. And when you say it "had to  2 match," what does that mean?  3 A. It couldn't be more than -- the  4 order couldn't be more than what was on the  5 222 form.  6 Q. Okay.  7 A. And the 222 form was -- was  8 received from the DEA.  9 Q. And so the DEA would tell  10 the -- would tell the --  11 A. Yes.  12 Q. -- your customer how much they  13 could order on a monthly basis?  14 A. I don't think it was on a  15 monthly basis. It was based -- I'm not sure.  16 I don't remember how the customer would get  17 their 222 form, but everybody in the quota  18 system -- the DEA would take -- the DEA would  19 take the total amount of a particular  20 product, like let's just say one product that  21 was sold in a particular year, and they would  22 look at that and that's the base of what we  23 are going to allow to be sold the following  24 year.  25 Some customers, like</p>
<p style="text-align: right;">Page 39</p> <p>1 form?  2 A. Quota forms were forms that  3 were used for raw material manufacturers.  4 222 forms were used for  5 researchers and other type of registrants and  6 also for the dosage customers who were  7 ordering Schedule II products.  8 Q. Okay. So you wouldn't need  9 both a quota form or a 22 form --  10 A. Right.  11 Q. -- or a 222 form.  12 It was one or the other?  13 A. Depending on their  14 registration.  15 Q. And for the 222 form, what  16 would that tell you?  17 A. Are we getting away from the  18 bulk side?  19 Q. Yes, why don't we focus on  20 dosage and then we can come back to bulk.  21 A. Okay.  22 Q. Because the 222 form isn't used  23 in connection with bulk, correct?  24 A. No, the 222 form had to match  25 the order that they were placing.</p>	<p style="text-align: right;">Page 41</p> <p>1 Mallinckrodt, would get a portion of that,  2 other manufacturers would get a portion of  3 that, and it was based upon their previous  4 sales. Okay. The same would be for the  5 distributors.  6 And that's what they would  7 start off with for the year, how much they  8 could buy, and the way that they bought it  9 was with a 222 form, which the DEA would give  10 them these forms in advance and they had --  11 they would, I guess, request more as they  12 needed them.  13 Q. Okay.  14 A. Just as long as it was within  15 their quota limits.  16 Q. So it sounds like there are  17 essentially two quotas being imposed:  18 There's one being imposed on Mallinckrodt,  19 and then there's another one --  20 A. As a manufacturer.  21 Q. Yes, one being imposed on  22 Mallinckrodt as a manufacturer. Thank you.  23 A. Right.  24 Q. And one being imposed on  25 Mallinckrodt's customers, which it sounds</p>

<p style="text-align: right;">Page 42</p> <p>1 like are distributors?</p> <p>2 A. If you're looking at the bulk</p> <p>3 side, again, we're a bulk manufacturer and</p> <p>4 we're selling to bulk manufacturers who add,</p> <p>5 so they would buy it on their procurement</p> <p>6 quota, okay, so they would send us a quota</p> <p>7 form, too.</p> <p>8 Q. Okay. So is the only</p> <p>9 difference between a quota form and a 222</p> <p>10 form the nature of the customer submitting</p> <p>11 the form?</p> <p>12 A. It's the nature of their</p> <p>13 registration.</p> <p>14 Q. Okay. And so focusing on the</p> <p>15 dosage products, let's say I'm a distributor</p> <p>16 and the DEA has given me a quota of</p> <p>17 50 million pills, let's say, for the year.</p> <p>18 A. Okay.</p> <p>19 Q. And Mallinckrodt has a quota</p> <p>20 of, you know, 200 million pills.</p> <p>21 A. Okay.</p> <p>22 Q. I take it this means that my</p> <p>23 222 form that I submit to Mallinckrodt can't</p> <p>24 exceed 50 million; is that right?</p> <p>25 A. How much did you say they had?</p>	<p style="text-align: right;">Page 44</p> <p>1 the 222 form was likely going to</p> <p>2 significantly exceed any monthly order that</p> <p>3 the customer placed; is that fair?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. So it's not as if the</p> <p>6 222 form is really directly limiting the</p> <p>7 monthly order of a customer.</p> <p>8 The check on how much that</p> <p>9 customer can order on a monthly basis would</p> <p>10 be Mallinckrodt's algorithm?</p> <p>11 A. Yes.</p> <p>12 Q. And that algorithm for the</p> <p>13 2000 -- the pre-2007 time period was based on</p> <p>14 two times your yearly average -- I'm sorry,</p> <p>15 your yearly monthly average?</p> <p>16 A. Are we speaking on bulk?</p> <p>17 Q. No, I was talking about dosage</p> <p>18 products.</p> <p>19 A. Oh, okay.</p> <p>20 I'm not -- I didn't have it at</p> <p>21 that time. I believe they did have a similar</p> <p>22 report, but I'm not sure what the algorithm</p> <p>23 was at the time. That came under Cathy</p> <p>24 Stewart's watch.</p> <p>25 Q. But for the bulk products that</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Well, my overall quota is</p> <p>2 50 million.</p> <p>3 A. Right.</p> <p>4 Q. For the entire year, though.</p> <p>5 A. Right.</p> <p>6 Q. So when I submit a 222 form to</p> <p>7 Mallinckrodt, I mean, I assume so long as the</p> <p>8 number is not higher than 50 million, then</p> <p>9 it's okay?</p> <p>10 I'm trying to sort of</p> <p>11 understand what the -- what the limit is for</p> <p>12 the specific 222 form in any given month.</p> <p>13 A. Well, keep in mind that they</p> <p>14 wouldn't be bringing in 50 million tablets</p> <p>15 into their inventory. They didn't want to</p> <p>16 keep that kind of inventory. And that,</p> <p>17 again, would call fall under the suspicious</p> <p>18 order monitoring program, so that large of a</p> <p>19 quantity at one time would be brought to the</p> <p>20 attention of the DEA, and the DEA would look</p> <p>21 into why they're ordering so much at one</p> <p>22 time.</p> <p>23 Q. Understood.</p> <p>24 But as a general matter, the</p> <p>25 222 form -- well, the quota being applied to</p>	<p style="text-align: right;">Page 45</p> <p>1 you were in charge of --</p> <p>2 A. Uh-huh.</p> <p>3 Q. -- the algorithm was two times</p> <p>4 the monthly average?</p> <p>5 A. From what I remember, that's</p> <p>6 true.</p> <p>7 Q. Okay.</p> <p>8 A. Rolling average.</p> <p>9 Q. And I'm sorry, what's the</p> <p>10 difference between a rolling average and --</p> <p>11 A. It's not a calendar -- it's not</p> <p>12 a calendar period. It's a 12-month period.</p> <p>13 Q. Okay. So it's still 12 months.</p> <p>14 It's just you don't go from January to</p> <p>15 January.</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And so in the bulk</p> <p>18 context, if my monthly average was, let's</p> <p>19 say, 50 kilograms --</p> <p>20 A. Okay.</p> <p>21 Q. -- I could go up to a hundred</p> <p>22 kilograms on my next order?</p> <p>23 A. Correct.</p> <p>24 Q. And then, of course, if I order</p> <p>25 a hundred kilograms, that would affect my</p>



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1 average.  
 2 A. Correct.  
 3 Q. And so, you know, over -- over  
 4 time, if you're using a two times algorithm,  
 5 you know, the monthly limit on what you can  
 6 order could increase significantly; isn't  
 7 that fair?  
 8 MR. TSAI: Object to the form.  
 9 THE WITNESS: It could.  
 10 QUESTIONS BY MR. KAWAMOTO:  
 11 Q. And was there any -- well, if  
 12 you were to look at --  
 13 A. But keep in mind --  
 14 Q. Sorry, go ahead.  
 15 A. But keep in mind, you know,  
 16 they could increase their -- what they were  
 17 ordering as long as it was within their quota  
 18 from the DEA.  
 19 Q. Understood.  
 20 A. And then outside of our monthly  
 21 report that went to the DEA, which the DEA  
 22 was fine with, okay, with what we used for  
 23 our criteria, we also -- the customer service  
 24 reps were quite familiar with who our  
 25 customers were and -- because there wasn't a

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1 huge number of bulk manufacturers that we  
 2 were dealing with, like there wasn't new  
 3 players all the time, so we had a pretty good  
 4 understanding of what their needs were.  
 5 So if there was something out  
 6 of the ordinary that our CSRs saw, they would  
 7 bring it to the attention of Karen Harper and  
 8 just make her aware of it if she felt there  
 9 was a need to look into it with the DEA or  
 10 whatever.  
 11 Q. And this is for the bulk  
 12 narcotics process, correct?  
 13 A. That's correct. That's what  
 14 we're speaking to, yes.  
 15 Q. And so in 2008, who took your  
 16 place in -- with respect to bulk narcotics?  
 17 Who assumed your position?  
 18 A. Cathy Stewart. So we switched.  
 19 Q. Okay. You switched.  
 20 And do you recall who has or do  
 21 you know who has your position now with  
 22 respect to dosage products?  
 23 A. No, I sure don't.  
 24 Q. Okay. So, sir, you're aware  
 25 that this case is about opioids; is that

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1 fair?  
 2 A. That's true, yes.  
 3 Q. Would you believe that there is  
 4 an opioid -- that there's an opioid crisis in  
 5 this country?  
 6 A. That's what I have heard, yes.  
 7 Q. And when you say that that's  
 8 what you've heard, what do you mean by that?  
 9 A. Well, on the news and that,  
 10 I've heard that there's been an opioid  
 11 epidemic, yes.  
 12 Q. And you believe that's  
 13 accurate?  
 14 A. I can only, you know -- from  
 15 what I've heard. I don't know personally.  
 16 Q. But you don't have any reason  
 17 to believe that that's -- that that's not  
 18 true?  
 19 A. No.  
 20 Q. Do you believe that the drugs  
 21 sold by Mallinckrodt contributed to this  
 22 epidemic?  
 23 A. That's a -- that's a -- no, I  
 24 don't believe that, and why I say that is  
 25 Mallinckrodt was -- was at the top of the --

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1 what I'll call the chain in that we  
 2 manufactured the product. We did not  
 3 manufacture the -- we manufactured it, we  
 4 shipped it, sold it to our distributors, the  
 5 distributors sold it to the pharmacies, the  
 6 pharmacies sold it to the physicians and the  
 7 physicians sold it to -- or prescribed it to  
 8 the patients. We were not in the position  
 9 to, I guess, ever send the pills to an end  
 10 user.  
 11 Q. Well, when you say that there  
 12 is an opioid epidemic, what's your  
 13 understanding of the nature of the epidemic?  
 14 A. I didn't say -- I agree with  
 15 you that I believe that from what I've heard  
 16 that there is.  
 17 Q. Okay. So you've heard that --  
 18 you've heard there's an opioid epidemic?  
 19 A. Uh-huh.  
 20 Q. What is your understanding of  
 21 the nature of that epidemic?  
 22 A. Well, it's from diversion of  
 23 not only prescription medicine but from  
 24 illegal products that are coming from other  
 25 countries, that type of thing. It's not --



1 it's not all prescribed or prescription,  
 2 controlled medication.  
 3 Q. Would you agree that the  
 4 prescription controlled medication is a  
 5 significant component of this epidemic?  
 6 A. I -- from what I've read or  
 7 heard.  
 8 Q. And when you say "diversion,"  
 9 what do you mean by that?  
 10 A. It's not being prescribed for  
 11 its intended use.  
 12 Q. And when you say "prescribed  
 13 for its intended use," what does that mean?  
 14 A. For medical purposes. For the  
 15 control -- what I consider medical use is  
 16 that the pills -- or the product that we sold  
 17 to other manufacturers who made a finished  
 18 good, intended use was for pain relief, okay,  
 19 and for people that were suffering from  
 20 long-term illness that needed pain relief,  
 21 cancer patients, surgery, people that had  
 22 surgery, that's what the intended use of the  
 23 opiates that we sold were for.  
 24 Q. And I'm just reading along --  
 25 I'm just reading on the screen, but you

1 indicated that your understanding is that the  
 2 products being sold by Mallinckrodt were for  
 3 long-term illness that needed pain relief,  
 4 cancer patients and surgery, essentially  
 5 cancer pain or acute pain; is that fair?  
 6 A. Some of that, yeah. Some of  
 7 the major applications.  
 8 Q. Okay. Do you understand what  
 9 chronic pain is?  
 10 MR. TSAI: Objection to the  
 11 form.  
 12 Go ahead.  
 13 THE WITNESS: Chronic pain is  
 14 from -- what my understanding of it is  
 15 is for people that are constantly in  
 16 pain. Okay. I can say like my  
 17 brother-in-law who has a chronic pain  
 18 in his back, and it's just every day  
 19 is a hard time getting out of bed.  
 20 QUESTIONS BY MR. KAWAMOTO:  
 21 Q. And so in your opinion should  
 22 he be on opioids?  
 23 MR. TSAI: Object to the form.  
 24 Go ahead.  
 25 THE WITNESS: In my opinion?

1 QUESTIONS BY MR. KAWAMOTO:  
 2 Q. Yes.  
 3 A. That's up to his doctor.  
 4 Q. Do you believe that opioids are  
 5 addictive?  
 6 A. I believe that they can be  
 7 addictive if they're abused.  
 8 Q. And do you believe that opioids  
 9 are being abused?  
 10 A. From my understanding and what  
 11 I've heard, yes, they can be abused.  
 12 Q. Okay. And what are the risk  
 13 factors for opioid abuse? Do you know what  
 14 any of them are?  
 15 A. I'm not familiar with it.  
 16 Q. Now, I just wanted to make sure  
 17 I understood your -- your understanding of  
 18 what the term "diversion" is.  
 19 But what -- could you define  
 20 "diversion" for me?  
 21 A. The way I think of diversion is  
 22 that the -- something that is being used  
 23 for -- is not being used for its intended use  
 24 I guess is the simplest way I can think of  
 25 it.

1 Q. And when you say "not being  
 2 used for its intended use," what do you mean  
 3 by that?  
 4 Are you talking about the  
 5 doctor is not appropriately prescribing it,  
 6 or what -- what do you mean by "not being  
 7 used for intended use"?  
 8 A. I guess that that would be part  
 9 of it, yes, that the doctor is prescribing  
 10 maybe more than what the patient needs or  
 11 product is being brought over from other  
 12 countries, that type of thing. It's not for  
 13 its intended use as a medical need, I guess.  
 14 Q. So the fact that a patient is  
 15 taking an opioid pursuant to a prescription  
 16 doesn't necessarily mean that the patient is  
 17 not abusing opioids; is that fair?  
 18 A. Saying that again?  
 19 Q. The fact that a patient is  
 20 taking opioids pursuant to a prescription  
 21 from a doctor --  
 22 A. Pursuant to a prescription.  
 23 Q. -- does not mean that the  
 24 patient -- well, strike that. Let me reask  
 25 that question.

<p style="text-align: right;">Page 54</p> <p>1 A doctor could misprescribe 2 opioids; is that fair? 3 A. I guess they could. 4 Q. And you've indicated that would 5 be one example of diversion? 6 A. Yes. 7 Q. Okay. So if you had a patient 8 that was taking opioids pursuant to a 9 prescription that was improper, that patient 10 would be abusing opioids, notwithstanding the 11 fact they had a prescription? 12 MR. TSAI: Object to the form. 13 THE WITNESS: I guess -- I 14 guess that's possible. 15 QUESTIONS BY MR. KAWAMOTO: 16 Q. And so in terms of what the 17 problems are with diversion or what the harms 18 are with diversion, what in your opinion are 19 the problems or harms stemming from 20 diversion, the diversion of opioids? 21 MR. TSAI: Object to the form. 22 THE WITNESS: In my opinion as 23 a layman? 24 QUESTIONS BY MR. KAWAMOTO: 25 Q. Well, in your opinion as</p>	<p style="text-align: right;">Page 56</p> <p>1 the DEA changed their needs, our requirements 2 for us, I felt we had the controls in place 3 to meet that. 4 Q. Did others at Mallinckrodt ever 5 express any concerns to you regarding 6 diversion of Mallinckrodt products, opioid 7 products? 8 A. That there was a diversion 9 problem? 10 Q. That there either was a 11 diversion problem or that there was a risk of 12 Mallinckrodt products being diverted? 13 A. No. 14 MR. TSAI: Objection. 15 Compound. 16 Go ahead. 17 THE WITNESS: No, not that I 18 remember. Everybody -- everybody was 19 doing what they could in making sure 20 that we were meeting the needs of 21 the -- meeting the DEA compliance 22 needs. 23 QUESTIONS BY MR. KAWAMOTO: 24 Q. And did you understand 25 diversion to be an issue of corporate concern</p>
<p style="text-align: right;">Page 55</p> <p>1 someone that's worked for Mallinckrodt from 2 1976 to 2013 and spent the past -- well, the 3 past 12-plus years in their business. 4 A. Well, I would say if they 5 weren't using it for its intended use as a 6 medicinal pain reliever, then I guess it 7 could be abused. And if they abused it, they 8 could be -- become medically dependent on it. 9 Q. And so diversion, one of the 10 consequences of diversion, could be abuse and 11 addiction; is that fair? 12 A. Correct. 13 Q. Did you ever have any concerns 14 about diversion while you were working for 15 Mallinckrodt? 16 A. It was always a concern that we 17 have the proper tools in place to keep that 18 from happening, and I felt that we did with 19 the regulations that we filed -- that were 20 given to us by the DEA as far as needing the 21 222 forms, in the bulk side, the quota forms. 22 Also we had the necessary data collection 23 that the DEA asked us to submit to them, 24 which went from the monthly letters to a more 25 sophisticated reporting system. Later on as</p>	<p style="text-align: right;">Page 57</p> <p>1 for Mallinckrodt? 2 A. I believe it was a corporate 3 concern, and that's one of the reasons why 4 our controls were so -- so tight. 5 Q. And when you say your "controls 6 were so tight," what controls are you talking 7 about? Could you list them for me? 8 A. Well, what I mean by that is 9 what we've discussed already is that we were 10 meeting the compliance of the DEA regulations 11 with requiring the quota letters and the 222 12 forms, which were required, also the letter 13 that we -- and bulk, also on dosage, that we 14 were asked to submit on a monthly basis early 15 on. And then as the regulations -- or as the 16 DEA tightened their regulations and asked us 17 to submit more than just the letters and 18 actually end the letters and to come up with 19 a more robust -- more robust suspicious order 20 monitoring program, we did that going 21 forward. 22 I always felt that Mallinckrodt 23 was a -- felt that it was very important as a 24 citizen -- I'm calling Mallinckrodt as a 25 citizen -- to adhere and meet the needs of</p>

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1 what the DEA was requiring over and beyond  
2 anything. That was kind of our corporate  
3 goal, I guess I would say.

4 MR. TSAI: Dean, we've been  
5 going about an hour.

6 MR. KAWAMOTO: Sure, why don't  
7 we take -- why don't we take a  
8 ten-minute break.

9 VIDEOGRAPHER: We're going off  
10 the record at 10 a.m.

11 (Off the record at 10:00 a.m.)

12 VIDEOGRAPHER: We're back on  
13 the record at 10:21 a.m.

14 QUESTIONS BY MR. KAWAMOTO:

15 Q. So, Mr. Rausch, you indicated  
16 that in 2008 you and Cathy Stewart  
17 essentially switched jobs.

18 A. Yes.

19 Q. So you went to dosage products,  
20 and she went to bulk narcotics.

21 A. That's correct.

22 Q. Why did you switch?

23 A. Our boss at the time, George  
24 Saffold, wanted us to switch to learn more  
25 about the other areas.

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1 Q. And "the other areas" meaning  
2 he wanted you to learn more about dosage  
3 products and her to learn more about bulk  
4 narcotics?

5 A. That's correct, right.

6 Q. Did George have any concerns  
7 about Cathy's stewardship of the dosage  
8 products?

9 A. No.

10 MR. TSAI: Object to the form.

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. Okay. And would you view your  
13 switch in 2008 as a promotion for you?

14 A. No, it was a lateral.

15 Q. Now, do you recall our prior  
16 discussion regarding the quota system?

17 A. Yes.

18 Q. Okay. And so I want to focus  
19 now on bulk narcotics with respect to the  
20 quota system.

21 Well, I guess why are quotas  
22 important?

23 A. Quotas are important -- and  
24 again, I'm speaking as a customer service  
25 person. I'm not, you know, privy to all the

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1 regulations that, like, Karen Harper in the  
2 compliance group would be.

3 But from what I remember, the  
4 quota system was important in -- for the DEA  
5 to keep track of what was being used in the  
6 United States. So like I had mentioned  
7 earlier, the DEA would take all the quota,  
8 all the -- all the quota letters and forms  
9 and the 222 forms that were used -- and I'm  
10 not only talking, you know, from the  
11 distributors but also from the pharmacists  
12 and everyone else that had to report to the  
13 DEA what they were using during the year --  
14 they would take that, add it all up and see  
15 what the total was for United States for a  
16 particular product. And they would use that  
17 for their base for what they were going to  
18 allow the following year. So that's why the  
19 reporting through the quota system was very,  
20 very important.

21 Q. And you had indicated that the  
22 compliance with the quota system was an  
23 element of Mallinckrodt's efforts to fight  
24 diversion; is that fair?

25 A. Well, I wouldn't say it was

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1 that. You know, it was to meet the  
2 regulations that were given to us by the DEA.

3 As a good citizen, Mallinckrodt  
4 being a good citizen, we felt it was very  
5 important that we follow the regulations in  
6 that to keep something like diversion from  
7 happening.

8 Q. And so what are -- what are all  
9 of the steps -- focusing now on the bulk  
10 narcotics side, what are all of the steps  
11 that Mallinckrodt took to ensure that the  
12 quota system was being complied with?

13 A. We would -- we would require  
14 from our customers, along with their order,  
15 to send us a quota form under their license,  
16 whether they're a manufacturer or a  
17 researcher or whatever license they had, they  
18 had to send us a quota form, and we would not  
19 use -- we could not ship that order until  
20 that form was sent to us. And what we would  
21 do with the quota form is then turn that into  
22 our compliance group.

23 Q. And did the -- did the quota  
24 form indicate their overall quota for the  
25 year?

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1 A. No, usually it was the amount  
2 that they were ordering. It couldn't be more  
3 than what was on the order.

4 Q. And so how -- how would  
5 Mallinckrodt know that this order -- that the  
6 order -- that the newest order your customer  
7 had submitted didn't exceed their quota for  
8 the year?

9 A. It would show the total, I  
10 believe, if I'm -- and I'm trying to  
11 remember. I think it would show the total,  
12 but then it would also show what they're  
13 using for that particular order.

14 Q. And when you say "total," I'm  
15 sorry, what total are you referring to?

16 A. You're asking what -- how we  
17 knew what the customer's total was?

18 Q. My apologies. So let me  
19 rephrase that question.

20 The quota form which showed the  
21 total amount of that narcotic they had  
22 received that year?

23 A. That they were ordering from  
24 us.

25 Q. Okay. Understood. But I guess

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1 my question may be a little different.

2 So let's say the DEA gives  
3 Manufacturer A a quota of a hundred  
4 kilograms?

5 A. Uh-huh.

6 Q. And Mallinckrodt -- and they  
7 submit an order to Mallinckrodt asking to  
8 purchase 3 kilograms.

9 A. Okay.

10 Q. How does Mallinckrodt know  
11 that -- whether that 3-kilogram order is  
12 going to exceed their hundred-kilogram quota?

13 A. It would show the total and  
14 then what had been used so far, from what I  
15 remember.

16 Q. So your recollection is that  
17 the quota form is going to show their overall  
18 quota, so a hundred kilograms?

19 A. Right.

20 Q. Plus the amount that they had  
21 ordered up -- so the total amount they had  
22 ordered thus far for the year?

23 A. I believe so, from what I  
24 remember.

25 Q. And was that just orders for

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1 Mallinckrodt, or was that all orders?

2 A. It would be all orders.

3 Q. Okay. So if Manufacturer A  
4 were ordering, you know, bulk product from  
5 Mallinckrodt and three other manufacturers,  
6 the quota form is going to show the total  
7 amount they had received from all of those  
8 other manufacturers?

9 A. Yes.

10 Q. And did Mallinckrodt take any  
11 steps to ensure that those numbers were  
12 accurate?

13 A. Customer service wasn't  
14 responsible for that, so we would turn in the  
15 forms to our -- to compliance groups, so that  
16 would be for them to determine that. They  
17 reported through their system, which was the  
18 ARCOS system, which I'm not that familiar  
19 with, but that's how they reported what the  
20 manufacturer or our customers had taken from  
21 us or sold to them from us.

22 Q. And ARCOS would tell you how  
23 much -- ARCOS would give you the amount of  
24 product that the manufacturer had obtained  
25 from Mallinckrodt.

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1 Would it also provide you with  
2 the information as to how much they had  
3 obtained from everyone else?

4 A. I would to refer you to Karen  
5 Harper on that.

6 Q. And going over to the dosage  
7 side, what was the system in place on the  
8 dosage side to ensure that the quota system  
9 was being complied with?

10 A. The customer had to give us a  
11 222 form that matched the order quantity that  
12 they were ordering, and that 222 form would  
13 then sent -- be sent to our compliance  
14 person, and they would gather all that --  
15 those compliance forms, I believe, on a  
16 monthly basis and send them to the DEA.

17 But, again, that's the  
18 compliance group, and I would refer you to  
19 them for more information.

20 Q. And did the 222 form also  
21 contain the total quota assigned to that  
22 distributor?

23 A. No, I don't believe it did,  
24 from what I remember. It was just for that  
25 particular order.



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1 Q. So I guess going back to my  
2 question from the bulk side.  
3 A. Uh-huh.  
4 Q. With respect to the dosage side  
5 of the business, how did Mallinckrodt know  
6 that -- well, strike that.  
7 So let's take the following  
8 hypothetical: Distributor A has a quota from  
9 DEA for a hundred pills.  
10 A. Uh-huh.  
11 Q. It submits a 222 form to  
12 Mallinckrodt asking to buy ten pills.  
13 How does Mallinckrodt know that  
14 those ten pills don't exceed the hundred-pill  
15 quota?  
16 A. We probably wouldn't, but  
17 remember that the DEA is issuing the 222  
18 form, so they -- as we turn in -- or we and  
19 whoever else they're buying from -- the 222  
20 forms back to the DEA, the DEA would give  
21 them new 222 forms based upon what was left.  
22 Q. And do you know how DEA set the  
23 quotas?  
24 A. No, that would be a Karen  
25 Harper question.

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1 Q. But you would agree that it's  
2 very important to comply with that quota  
3 system?  
4 A. Oh, yes.  
5 Q. So we previously spoke about  
6 diversion.  
7 Do you recall that?  
8 A. Yes.  
9 Q. And is it your understanding  
10 that Mallinckrodt products were being  
11 diverted?  
12 A. Is it my understanding?  
13 Not that I'm aware of. Just  
14 from what -- I guess what I've heard from the  
15 news.  
16 Q. Well, but you've seen news  
17 reports indicating that Mallinckrodt products  
18 have been diverted; is that fair?  
19 A. Yes. Yes.  
20 Q. And do you recall what those  
21 news reports said?  
22 A. No, not really.  
23 Q. But your understanding from  
24 these news reports is that Mallinckrodt  
25 products were being diverted and they were

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1 being abused; is that fair?  
2 A. Correct.  
3 Q. Are you familiar with the term  
4 "Ms"?  
5 A. Ms?  
6 Q. Ms.  
7 A. No, I'm not.  
8 Q. Okay. What about "Mollies"?  
9 A. Mollies?  
10 I've heard of them, but I don't  
11 know specifically what they are.  
12 Q. Okay. Are you familiar -- are  
13 you familiar with any terms or any references  
14 to Mallinckrodt products with respect to  
15 being street drugs?  
16 A. No.  
17 Q. So given that Mallinckrodt  
18 products were being diverted and they were  
19 being abused, are there any additional steps,  
20 looking back in hindsight, that you feel  
21 Mallinckrodt should have taken?  
22 A. Well, I just want to say that  
23 if you remember where we were in the chain of  
24 manufacturing, if we're talking about bulk at  
25 this time -- are we talking about 2007? Are

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1 we talking generic? What time frame?  
2 Q. Let's start with dosage  
3 products and then we can go to bulk.  
4 A. Okay. Okay.  
5 Keep in mind that the generic  
6 business, we were -- you know, we had our own  
7 regulations in place of meeting the DEA  
8 requirements, plus we developed our  
9 suspicious order monitoring program, which  
10 was another step of identifying orders that  
11 may have been out of order or suspicious  
12 quantities.  
13 And when we sold those, sold  
14 our product, they went to distributors who  
15 were supposed to have their own suspicious  
16 order monitoring programs in place, and then  
17 they sold to druggists and then to physicians  
18 and then to the end user.  
19 So there was a -- quite a  
20 number of people in between Mallinckrodt and  
21 the end user, so I would say that we did  
22 our -- our due diligence in trying to keep  
23 diversion from happening.  
24 Q. And when you say "due  
25 diligence," what do you mean by that?



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1 A. By -- by meeting the  
2 requirements of the DEA.  
3 Q. And so it was very important to  
4 you that Mallinckrodt meet these DEA  
5 requirements?  
6 A. I would say it's probably the  
7 most important thing that we did.  
8 Q. And this view was widely shared  
9 at the company; is that correct?  
10 A. Yes, it was.  
11 I will add that when we were  
12 developing our suspicious order program, that  
13 that was rolled out to our marketing people  
14 and also our sales force on what our  
15 requirements were and what their part would  
16 be going forward in helping us on -- on  
17 controlling any -- any possible suspicious  
18 orders or peculiar orders as we -- it became  
19 known as later on.  
20 Q. How did you know that your  
21 suspicious order monitoring program was  
22 effective?  
23 A. We did not have one suspicious  
24 order while I was doing the job.  
25 Q. And when you say you did not

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1 have one suspicious order while you were  
2 doing the job, what do you mean by that?  
3 A. Well, just to talk a little bit  
4 about the suspicious order program that we  
5 developed, an order would be flagged every  
6 day -- an order could be flagged on a daily  
7 basis as being suspicious or peculiar, as we  
8 called it, and what that is, is just a stage  
9 that we went through.  
10 If an order was flagged as  
11 being peculiar, it was during my time, my job  
12 or responsibility to talk to marketing or our  
13 customer service reps, who would be the first  
14 people that I would talk to because they were  
15 in tuned to our customers and what their  
16 order needs were, and they would know if  
17 there was anything unusual as far as a  
18 distributor picking up a new customer that  
19 they hadn't had before that they would now  
20 need increased material to supply.  
21 And if our CSR did not have  
22 a -- an answer to why the customer was  
23 ordering more, I would go to the product  
24 manager, or business manager, whatever they  
25 were being called at the time, who had that

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1 particular product that the order was for,  
2 and I would ask them if they knew why all of  
3 a sudden we were having a peculiar order from  
4 that customer.  
5 And a peculiar order, again,  
6 would be unusual quantity from what they have  
7 bought in the past over a period of time  
8 based upon the log rhythms {sic} we set in  
9 place in our computer system.  
10 If they didn't know, my next  
11 step would be going to the salesperson and  
12 asking them.  
13 Q. And so when you say that you  
14 didn't have any suspicious orders, though,  
15 what do you mean -- what do you mean by that?  
16 A. Suspicious order is one that  
17 would be -- where there is possible -- where  
18 we could not identify for whatever -- what  
19 reason the customer was ordering more than  
20 what they had in the past. That would become  
21 a suspicious order. And we report that to  
22 Karen Harper and her group, who would then  
23 report it to the DEA.  
24 Q. And so I just want to make sure  
25 I understand what your testimony is.

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1 Are you saying that because  
2 none of your customers ever submitted a  
3 suspicious order to you, that your suspicious  
4 order monitoring program was effective?  
5 MR. TSAI: Object to the form.  
6 THE WITNESS: I'm saying that  
7 during the time that I was running the  
8 program and working the program that  
9 we did not have a suspicious order.  
10 QUESTIONS BY MR. KAWAMOTO:  
11 Q. And when you say you "did not  
12 have a suspicious order," that means that you  
13 didn't identify any orders that were  
14 suspicious?  
15 A. We identified orders that were  
16 peculiar, but we could explain them and did  
17 not go to the point of being a suspicious  
18 order.  
19 Q. And I guess my question is, I  
20 mean, you've indicated that you could explain  
21 all of your peculiar orders.  
22 How do you know that -- that  
23 your explanations were, in fact, correct?  
24 A. Because in identifying the --  
25 why the order was being determined being

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1 peculiar, we had a legitimate explanation of  
2 why the order was larger or peculiar from  
3 what it had been in the past, increased  
4 sales, a new customer was coming aboard that  
5 the customer of ours had gotten. They were  
6 explainable orders is what I'm saying. So,  
7 therefore, they went to peculiar order to  
8 legitimate order.

9 Q. And the explanation you were  
10 getting, though, was ultimately being  
11 provided by the customer; is that accurate?

12 A. By the -- by the -- well, from  
13 the salesman or from marketing or the product  
14 manager in dealing with the customer.

15 Q. So they would get the  
16 information from the customer --

17 A. Correct.

18 Q. -- and relay it to you?

19 A. At that -- yes.

20 Q. Was there ever a circumstance  
21 why a customer lied to one of your sales  
22 reps?

23 A. I don't know that.

24 Q. If the customer lied to your  
25 sales rep, then, in fact, the order would not

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1 be legitimate; is that correct?

2 MR. TSAI: Object to the form.  
3 Go ahead.

4 THE WITNESS: That's possible,  
5 but what I'm saying that from when I  
6 was working at, we were -- we were  
7 satisfied with explanations that we  
8 were receiving from our sales force  
9 and the marketing folks why the order  
10 was legitimate.

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. Are you familiar with the  
13 compensation scheme for your sales force?

14 A. No, I'm not.

15 Q. Do you know if their bonus was  
16 dependent in any way on the number of sales  
17 they made?

18 A. Well, I would guess that sales  
19 would be involved, but keep in mind that the  
20 sales force were very aware of the DEA  
21 compliance that Mallinckrodt enforced and  
22 they knew it could lead to firing or us  
23 losing our license to manufacture and sell.  
24 So it was a high priority for us over and  
25 beyond sales.

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1 Q. Was the sales force's  
2 compensation based upon their -- strike that.

3 Was the sales force's  
4 compensation in any way based upon their  
5 compliance with the DEA regulations?

6 MR. TSAI: Object to the form.

7 THE WITNESS: I can't -- I  
8 can't answer that. I don't know.

9 (Mallinckrodt-Rausch Exhibits 1  
10 and 2 marked for identification.)

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. I would like to mark this as  
13 Exhibit 1.

14 And actually this Exhibit 1  
15 goes in connection with Exhibit 2, so I'm  
16 going to mark that as well.

17 So. Mr. Rausch, I've handed  
18 you two exhibits. The first one is an e-mail  
19 chain and it bears the Bates number  
20 MNK-T1\_273559. That's Exhibit 1.

21 And then I've also provided you  
22 with an exhibit marked Exhibit 2. This is a  
23 letter from the DEA, and it's dated  
24 September 27, 2006, and it bears a Bates  
25 number MNK-T1\_273563.

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1 A. Okay.

2 Q. Do you have both exhibits, sir?

3 A. I do.

4 Q. So directing your attention to  
5 the e-mail if the very top of the e-mail  
6 chain?

7 A. Which -- on Exhibit 1?

8 Q. On Exhibit 1.

9 A. Okay.

10 Q. Do you see the second paragraph  
11 that says, "Please note that Vince Kaiman and  
12 I had a conversation"?

13 A. Yes.

14 Q. Okay. And this is an e-mail  
15 from Karen Harper, but she's indicating that  
16 she shared a DEA letter with you.

17 Do you see that?

18 A. Correct.

19 Q. Okay. And Exhibit 2 I believe  
20 is that letter.

21 A. I want to look at that now?

22 Q. Yes. Could you look at that?

23 A. Okay.

24 Q. Do you recall Karen Harper  
25 sharing this letter from you -- with you?

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1 A. I don't.  
 2 Q. Okay.  
 3 A. Just because I don't remember  
 4 seeing it. It's been a long time.  
 5 Q. Sure.  
 6 But do you recall receiving  
 7 this letter at some point?  
 8 A. I don't recall it, but that  
 9 doesn't mean I didn't receive it.  
 10 Q. Okay. Do you recall ever  
 11 reviewing a letter like this?  
 12 A. Yes.  
 13 Q. And why did you review this  
 14 letter?  
 15 A. Can I --  
 16 Q. Absolutely.  
 17 A. Can I take a look at it?  
 18 Q. Yes. Actually, why don't you  
 19 review that letter and let me know when  
 20 you're ready.  
 21 A. Okay. Okay.  
 22 Q. So directing your attention to  
 23 the second page of this letter, it bears the  
 24 Bates number 273564, do you see the third  
 25 paragraph from the bottom? It starts, "Thus

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1 in addition."  
 2 A. Okay.  
 3 Q. And can you read that paragraph  
 4 into the record for me?  
 5 A. "Thus, in addition to reporting  
 6 all suspicious orders, a distributor has a  
 7 statutory responsibility to exercise due  
 8 diligence to avoid filling suspicious orders  
 9 that might be diverted into other than  
 10 legitimate, medical, scientific and  
 11 industrial channels. Failure to exercise  
 12 such due diligence could, as circumstances  
 13 warrant, provide a statutory -- statutory  
 14 basis for revocation or suspension of the  
 15 distributor's registration."  
 16 Q. Now, did you understand that  
 17 that legal requirement also applied to  
 18 Mallinckrodt as a manufacturer?  
 19 MR. TSAI: Object to the form.  
 20 Go ahead.  
 21 THE WITNESS: Yes.  
 22 QUESTIONS BY MR. KAWAMOTO:  
 23 Q. Okay. And then do you see in  
 24 the paragraph beneath that, it says, "A  
 25 distributor may not simply rely on the fact

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1 that the person placing the suspicious order  
 2 is a DEA registrant and turn a blind eye to  
 3 the suspicious circumstances."  
 4 Do you understand that to also  
 5 require -- also apply to Mallinckrodt as a  
 6 manufacturer?  
 7 A. Yes.  
 8 Q. Okay. Then turning to page 3  
 9 of the memo. It says, "Circumstances that  
 10 might be indicative of diversion." It  
 11 identifies four -- four circumstances.  
 12 Would you agree that those  
 13 circumstances are ones that are indicative of  
 14 diversion?  
 15 A. Certain pharmacies have engaged  
 16 in dispensing controls.  
 17 Those are four circumstances  
 18 that could lead to diversion, yes.  
 19 Q. And so if a distributor -- if a  
 20 distributor's order fell within one of these  
 21 four circumstances, you would agree that that  
 22 is potentially a suspicious order, would you  
 23 not?  
 24 A. Peculiar order, yes.  
 25 Q. Then below that, there's --

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1 there's a paragraph below that with ten  
 2 questions.  
 3 Do you see that?  
 4 A. Yes.  
 5 Q. So the first question is:  
 6 "What percentage of the pharmacy's business  
 7 does dispensing controlled substances  
 8 constitute?"  
 9 Would you agree that that is  
 10 important information to have and evaluate  
 11 whether an order is suspicious?  
 12 A. For the distributor?  
 13 Q. Yes.  
 14 A. I would say yes.  
 15 Q. And then if you were to change  
 16 this question so that it be what percentage  
 17 of the distributor's business does dispensing  
 18 controlled substances constitute, would you  
 19 agree that that's important information for  
 20 Mallinckrodt to have with respect to its  
 21 customer?  
 22 A. Yes.  
 23 Q. Okay. And so for number 2 it  
 24 says: "Is the pharmacy compliant with the  
 25 laws of every state in which it is dispensing

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1 controlled substances?"  
 2 If you were to substitute, you  
 3 know, one of Mallinckrodt's customers in for  
 4 "pharmacy," would you agree that's important  
 5 information for Mallinckrodt to have?

6 A. Yes.

7 Q. Okay. So looking at these -- I  
 8 guess the remaining ten questions, in an  
 9 effort to try to truncate things, would you  
 10 agree that all of these questions, as applied  
 11 to Mallinckrodt's customers, are important  
 12 information for Mallinckrodt to have in  
 13 assessing whether an order is peculiar?

14 MR. TSAI: Object to the form.

15 THE WITNESS: No, not all of  
 16 them would apply to our business of  
 17 selling to the distributors.

18 QUESTIONS BY MR. KAWAMOTO:

19 Q. Okay. Which ones would not  
 20 apply?

21 A. Well, does the pharmacy fill  
 22 prescriptions issued by practitioners based  
 23 solely on an online questionnaire without a  
 24 medical exam or bona fide doctor-patient  
 25 relationship.

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1 Do you want me to go through  
 2 all of them and tell you which ones I don't  
 3 think would apply?

4 Q. Yes, I think that would be  
 5 helpful.

6 So I have number 5 and then...

7 A. Number 3.

8 Q. Okay.

9 A. Number 4.

10 Number -- well, number 8 is  
 11 something that we wouldn't -- wouldn't be  
 12 part of.

13 Number 9.

14 Number 10.

15 Q. And your basis for identifying  
 16 these is because Mallinckrodt doesn't do  
 17 business directly with pharmacies; is that  
 18 correct?

19 A. Correct.

20 Q. Okay. Does Mallinckrodt do  
 21 business with retail pharmacies, though? For  
 22 example, you know, CVS or Walgreens?

23 A. With chains.

24 Q. With pharmacy chains?

25 A. Right.

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1 Q. And so if a pharmacy chain fell  
 2 into any one of these six categories,  
 3 wouldn't that be of concern to Mallinckrodt?

4 MR. TSAI: Object to the form.

5 THE WITNESS: I would guess so.

6 QUESTIONS BY MR. KAWAMOTO:

7 Q. Okay. So, for example, if you  
 8 had a retail pharmacy that was soliciting  
 9 buyers of controlled substances via the  
 10 Internet or is a pharmacy associated with the  
 11 Internet that solicits orders for controlled  
 12 substances, that would be of concern to  
 13 Mallinckrodt, would it not?

14 A. Yes.

15 Q. And modifying that question, if  
 16 you were -- if one of your distributors was  
 17 doing business with, for example, a pharmacy  
 18 or an Internet site affiliated with the  
 19 pharmacy offering to facilitate the  
 20 acquisition of a prescription for a  
 21 controlled substance from a practitioner with  
 22 whom the buyer has no preexisting  
 23 relationship, wouldn't that be of concern to  
 24 you?

25 A. We sold to the distributors,

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1 not -- your question was about the  
 2 distributor.

3 Q. Well, no, I'm sorry. Let me  
 4 rephrase that.

5 My question is now about the  
 6 distributors' customers.

7 A. Okay.

8 Q. So you've got a list here of  
 9 ten essentially -- would it be fair to call  
 10 these red flags?

11 A. Yes.

12 Q. Okay. So you've got a  
 13 question -- you've got a list here of ten red  
 14 flags.

15 If a distributor is doing  
 16 business with a pharmacy that raises one or  
 17 more red flags, wouldn't that be of concern  
 18 to Mallinckrodt?

19 MR. TSAI: Object to the form.

20 THE WITNESS: Well, it would be  
 21 a red flag for the distributor who  
 22 also has a suspicious order monitoring  
 23 program that should be in place.

24 Okay.

25 We were -- we were not



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1 monitoring our customers' customer at  
2 this time. We were asked to -- to  
3 monitor our customers or build a  
4 report -- a suspicious order program  
5 on our customers.

6 QUESTIONS BY MR. KAWAMOTO:

7 Q. And you said you're not  
8 monitoring them at this time.

9 A. Well, okay. We weren't  
10 monitoring them. When I had -- this is back  
11 in 2007. When I was in -- or in 2006,  
12 actually. When I didn't -- I was in the bulk  
13 area, not in the dosage area.

14 But our program was based upon  
15 the customers that we were selling to, not  
16 who our customers' customers were selling to.  
17 We didn't have that information available to  
18 us at that time.

19 Q. And do you know if --

20 A. Am I making myself clear?

21 Q. Well, I think so, but I want to  
22 make sure I understand what you're saying.

23 A. Okay.

24 Q. So with respect to the bulk  
25 area, which is prior to 2007 -- which is

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1 prior to 2007 --

2 A. Uh-huh.

3 Q. This letter is dated 2006.

4 You're saying that from -- from  
5 the standpoint of the bulk narcotics  
6 business --

7 A. Yes.

8 Q. -- you were not looking at your  
9 customers' customer; is that accurate?

10 A. That's correct.

11 Q. Okay.

12 A. And keep in mind, back then, we  
13 were sending a monthly letter to the DEA  
14 office, which I think I talked about earlier  
15 in our conversation. That was the  
16 requirement of the DEA at that time in 2006,  
17 and I believe into 2007, and then the DEA was  
18 telling us through our compliance group where  
19 we were getting the information like this and  
20 in talks with her that the letter was no  
21 longer needed. They didn't want to see the  
22 letter. They wanted us to start developing a  
23 program, which we would call our -- ongoing  
24 our suspicious order monitoring program,  
25 which we worked on for a period of time and

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1 was put in place in the end of 2008.

2 So from the bulk business, we  
3 were monitoring our customers, not their  
4 customers.

5 Q. But Mallinckrodt had the  
6 capability of monitoring your customers'  
7 customers, did it not?

8 A. On the bulk business?

9 No, not that I am aware of.

10 Q. Did it have the ability to do  
11 so on the dosage side?

12 A. From a customer service  
13 perspective, no.

14 Q. Well, you indicated a customer  
15 service perspective. I guess I would ask the  
16 question --

17 A. We did not have the resources  
18 to identify who our customer -- who our  
19 customer were selling to.

20 Q. And when you say "resources,"  
21 you're talking about you didn't have enough  
22 employees; you did not have enough staff?

23 A. No, we didn't have the data  
24 information available to us, that I'm aware  
25 of.

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1 Q. On the -- either on the dosage  
2 side or on the bulk side?

3 A. Well, are we bouncing back and  
4 forth?

5 On the bulk side, we did not.

6 Q. Okay. So on the bulk side, you  
7 did not have -- you did not have the data  
8 that would allow you to know who your  
9 customers' customer was?

10 A. Right.

11 Q. Now, turning to the dosage  
12 side --

13 A. Which I did not have at that  
14 time.

15 Q. Understood.

16 But turning to the dosage side  
17 prior to 2007 --

18 A. Right.

19 Q. -- did Mallinckrodt -- are you  
20 aware -- well, strike that.

21 Did Mallinckrodt have the  
22 ability to monitor its customers' customer?

23 A. I was not aware if it was or  
24 not.

25 Q. And when you say you're "not



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1 aware," is that -- strike that.  
 2 You don't know one way or the  
 3 other; is that fair?  
 4 A. Correct.  
 5 Q. Would Cathy Stewart know?  
 6 MR. TSAI: Object to the form.  
 7 THE WITNESS: I can't answer  
 8 that. I don't know what Cathy would  
 9 know about it.  
 10 QUESTIONS BY MR. KAWAMOTO:  
 11 Q. Okay. But in any event,  
 12 Mallinckrodt was not monitoring its  
 13 customers' customer on the dosage side prior  
 14 to 2007?  
 15 A. As far as I know, they were  
 16 not. They were -- they were doing the same  
 17 thing the bulk side was doing.  
 18 Q. Would you agree, though, that  
 19 from a standpoint of diversion control and  
 20 diversion prevention, it would be helpful to  
 21 know your customers' customer?  
 22 A. I can't answer that. I  
 23 don't -- I don't know the answer to that from  
 24 a diversion.  
 25 I mean, keep in mind I want to

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1 reiterate that we were not the only player in  
 2 this -- in this closed loop where we were  
 3 selling to our customer, our customer was  
 4 supposed to be monitoring their customer all  
 5 the way down to the pharmacist and the  
 6 doctor.  
 7 Q. Well, but I have a slightly  
 8 different question, which is: You know a  
 9 distributor is distributing to, let's say,  
 10 Internet pharmacies that are just filling  
 11 prescriptions, you know, over the Internet,  
 12 it's soliciting orders over the Internet, and  
 13 that's an area of concern, that's one of the  
 14 red flags raised in this 2006 letter, is it  
 15 not?  
 16 A. Yes.  
 17 Q. Okay. So you've got a  
 18 distributor and you know that distributor is  
 19 doing business with those types of  
 20 pharmacies; isn't that of concern to  
 21 Mallinckrodt?  
 22 A. I think that's one of the  
 23 reasons we put in our program on the  
 24 deviation of orders that were coming from our  
 25 customers to show if there was a suspicious

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1 order there. We couldn't tell who they were  
 2 selling to at that time.  
 3 If you're asking me did I  
 4 think -- do I feel that knowing our  
 5 customers' customer would benefit  
 6 Mallinckrodt or benefit the diversion? It's  
 7 possible, but I can't answer that for sure.  
 8 Q. Well, if Mallinckrodt, though,  
 9 had the ability to monitor its customers'  
 10 customer, would you --  
 11 A. Is that hypothetically?  
 12 Q. Hypothetically.  
 13 If they had the ability to do  
 14 that, would you agree that it would have been  
 15 helpful to diversion control for them to do  
 16 so?  
 17 MR. TSAI: Object to the form.  
 18 THE WITNESS: Yes, it would be  
 19 helpful.  
 20 QUESTIONS BY MR. KAWAMOTO:  
 21 Q. Okay. Do you believe it should  
 22 have been required?  
 23 A. I can't answer that. We were  
 24 meeting the requirements that I felt were in  
 25 place at the time.

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1 That's a -- that's a Karen  
 2 Harper question.  
 3 Q. So turning now -- I'm going to  
 4 focus your attention on two other -- two more  
 5 exhibits, and so I'm marking these in tandem  
 6 as Exhibit 3 and as Exhibit 4.  
 7 (Mallinckrodt-Rausch Exhibits 3  
 8 and 4 marked for identification.)  
 9 QUESTIONS BY MR. KAWAMOTO:  
 10 Q. This is Exhibit 3 and it bears  
 11 the Bates number MNK-T1\_419874.  
 12 And while I'm labeling things,  
 13 I'm going to also label Exhibit 4. This is a  
 14 DEA letter, and it bears a Bates number  
 15 MNK-T1\_421084.  
 16 A. Okay. You want me to read  
 17 this, or you want just --  
 18 Q. Actually, I just have a few  
 19 quick questions on this cover e-mail.  
 20 A. Okay.  
 21 Q. But it is an e-mail to -- from  
 22 Karen Harper to Cathy Stewart.  
 23 Do you see the second e-mail  
 24 that's dated -- the second e-mail from the  
 25 top dated March 12, 2008?

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1 A. Okay. Yes.  
 2 Q. It references attached  
 3 information that Karen had sent to you and  
 4 Michael Phenev.  
 5 Who is Michael Phenev?  
 6 A. Michael Phenev was my boss at  
 7 the time.  
 8 Q. And I believe the  
 9 attachments on -- the attachment to this  
 10 e-mail is this December 27, 2007 letter.  
 11 So if I could -- well, do you  
 12 recall Karen Harper sending you this -- this  
 13 letter?  
 14 A. No, I don't.  
 15 Q. Okay. Actually, I'm sorry, if  
 16 you look at the very bottom of the page,  
 17 there's an e-mail from Karen Harper dated  
 18 January 4, 2008, and you are -- you are one  
 19 of the cc's.  
 20 Do you see that?  
 21 A. Yes.  
 22 Q. Okay. Do you recall Karen  
 23 Harper sending you this e-mail?  
 24 A. No, it's been --  
 25 Q. Do you have any reason to doubt

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1 that she sent you this e-mail?  
 2 A. No, I don't.  
 3 Q. Okay. Could you please review  
 4 the December 27, 2007 letter? I believe  
 5 that's Exhibit 4.  
 6 A. Okay.  
 7 Q. Okay. So do you recall  
 8 reviewing this letter when you were employed  
 9 by Mallinckrodt?  
 10 A. I recall it.  
 11 Q. Okay. So directing your  
 12 attention to the third paragraph from the top  
 13 of the first page of the letter --  
 14 A. Okay.  
 15 Q. -- it said, "The regulation  
 16 also requires that the registrant inform the  
 17 local DEA division office of suspicious  
 18 orders when discovered by the registrant."  
 19 A. Okay.  
 20 Q. "Filing a monthly report of  
 21 completed transactions, e.g., an excessive  
 22 purchase report or high unit purchases, does  
 23 not meet the regulatory requirement to report  
 24 suspicious orders.  
 25 "Registrants are reminded that

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1 the responsibility does not end merely with  
 2 the filing of a suspicious order report.  
 3 Registrant must conduct an independent  
 4 analysis of suspicious orders prior to  
 5 completing a sale to determine whether the  
 6 controlled substances are likely to be  
 7 diverted from legitimate channels."  
 8 Do you understand that  
 9 language?  
 10 A. Yes.  
 11 Q. And is that -- is that a  
 12 correct statement of Mallinckrodt's  
 13 responsibilities under the law?  
 14 A. Yes.  
 15 Q. Okay. Further on down it  
 16 states, "The regulation specifically states  
 17 that suspicious orders include orders of an  
 18 unusual size, orders deviating substantially  
 19 from a normal pattern, and orders of an  
 20 unusual frequency. These criteria are  
 21 disjunctive and are not all inclusive."  
 22 Do you see that?  
 23 A. Yes.  
 24 Q. And do you understand what that  
 25 means?

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1 A. Yes.  
 2 Q. And is that an accurate  
 3 statement of what a suspicious order is?  
 4 A. Yes.  
 5 Q. Okay.  
 6 A. And then some.  
 7 Q. Okay. At the very bottom of  
 8 that paragraph it says, "The size of an order  
 9 alone, whether or not it deviates from a  
 10 normal pattern, is enough to trigger the  
 11 registrant's responsibility to report the  
 12 order as suspicious.  
 13 "The determination of whether  
 14 an order is suspicious depends not only on  
 15 the ordering patterns of the particular  
 16 customer but also on the patterns of the  
 17 registrant's customer base and the patterns  
 18 throughout the relevant segment of the  
 19 regulated industry."  
 20 Do you see that statement?  
 21 A. I do.  
 22 Q. And do you agree with it?  
 23 A. Yes.  
 24 Q. And so you understood this to  
 25 be an accurate statement of Mallinckrodt's

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1 legal responsibilities with respect to  
2 suspicious orders?  
3 A. From the bulk side, which is  
4 where I was at this time, this was where we  
5 started, from what I remember. Our St. Louis  
6 field office did not want to receive the  
7 monthly report any longer. Okay.

8 And we were instructed -- Karen  
9 Harper and Michael Pheney and some other  
10 folks put together a team of people to come  
11 up with a more robust suspicious order  
12 monitoring program, which included myself,  
13 Cathy. Karen Harper oversaw it, but she  
14 didn't come to all the meetings. We had a  
15 few IT people that was involved, to come up  
16 with a more robust ordering -- suspicious  
17 order monitoring program that would identify  
18 orders as being peculiar as the orders came  
19 through.

20 This was developed over time  
21 period of like 2000 -- in the 2000-2008 time  
22 period and put in place.

23 Q. And this -- I guess you would  
24 call --

25 A. This was kind of the precursor

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1 for that -- this kind of got the motion --  
2 wheels in motion for getting that done.

3 Q. So I take it -- and that's what  
4 I think you previously referred to as your  
5 enhanced suspicious order monitoring --

6 A. Correct.

7 Q. -- program, your enhanced SOM  
8 program?

9 A. Yes.

10 Q. And you would agree with me  
11 that that enhanced program was required to  
12 meet all of the requirements set forth in  
13 this letter, would you not?

14 A. Not only what was in this  
15 letter -- keep in mind the DEA did not tell  
16 us what should be in our program. They  
17 never -- they didn't tell us whether it was  
18 correct. They didn't want to see a program.  
19 They just told us that, "These are some of  
20 the things that we wanted to see in your  
21 program."

22 We did this stuff and included  
23 some other things that they thought were  
24 important.

25 Q. Okay. So this -- in other

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1 words, this was a floor, not a ceiling?

2 A. Correct.

3 Q. Okay. But it was -- it was  
4 critically important to Mallinckrodt that its  
5 enhanced SOM program meet, at a minimum, the  
6 requirements in this letter?

7 A. Yes.

8 Q. Okay. And so directing your  
9 attention to page 2, it says, "Registrants  
10 that rely on rigid formulas to define whether  
11 an order is suspicious may be failing to  
12 detect suspicious orders. For example, a  
13 system that identifies orders as suspicious  
14 only if the total amount of a controlled  
15 substance ordered during one month exceeds  
16 the amount ordered the previous month by a  
17 certain percentage or more is insufficient."

18 And so what is your  
19 understanding of what that requirement is?

20 A. Well, I think what they're  
21 saying is that it shouldn't be based on just  
22 what the previous month was -- what -- what  
23 previous month order might have been. Okay.

24 They're saying is that they  
25 want you to take a look at an ongoing -- what

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1 I'll call a floating month period, like I  
2 described earlier to you, a rolling time  
3 period. So it wasn't from calendar year. It  
4 was like January to January, February to  
5 February, so it kept moving depending on --  
6 so if you were in April, it was looking at  
7 orders that were placed from March to March,  
8 okay.

9 Q. Now, it also says that  
10 "Registrants that rely on rigid formulas to  
11 define whether an order is suspicious may be  
12 failing to detect suspicious orders."

13 A. That's exactly what I'm trying  
14 to describe to you right there. They're not  
15 saying don't look at what they ordered just  
16 the previous month. Look at what they've  
17 done over the previous 12 months or -- and in  
18 our case, we said, okay, we're going to look  
19 at a 12-month roving {sic} period of time.

20 Q. Okay. Doesn't this also tell  
21 you though that if all you're doing is  
22 relying on a rigid formula, on a numeric  
23 formula, that is also insufficient?

24 MR. TSAI: Object to the form.

25 THE WITNESS: Yeah, and that's

<p style="text-align: right;">Page 102</p> <p>1 what I'm trying to explain to you.</p> <p>2 Not only did we have this, what</p> <p>3 they're saying -- they say ordered</p> <p>4 during one-month period exceeds the</p> <p>5 amount ordered, that was rigid, that's</p> <p>6 what they considered rigid. Okay.</p> <p>7 What they were saying, don't</p> <p>8 rely on what they just ordered the</p> <p>9 previous month, that's what they</p> <p>10 considered rigid.</p> <p>11 So the rolling months was not</p> <p>12 rigid. Okay.</p> <p>13 We only -- we not only did</p> <p>14 rolling months, but we went in</p> <p>15 frequency over a period of time. We</p> <p>16 not only looked at a particular size,</p> <p>17 and I'm -- of a bulk product, and this</p> <p>18 also applies to the dosage because I'm</p> <p>19 thinking of dosage. Because we had</p> <p>20 different sizes of the same product.</p> <p>21 We would look at the family,</p> <p>22 okay, meaning combining all the</p> <p>23 products within, let's say,</p> <p>24 hydrocodone, we had several different</p> <p>25 sizes. So we would look at the bulks</p>	<p style="text-align: right;">Page 104</p> <p>1 Indicative of Diversion."</p> <p>2 I'm sorry, it's actually page 3</p> <p>3 of the letter.</p> <p>4 A. Okay. Page 3.</p> <p>5 At the top?</p> <p>6 Q. Yes.</p> <p>7 A. Okay.</p> <p>8 Q. You would agree that --</p> <p>9 A. Again, we're looking at</p> <p>10 pharmacies, right?</p> <p>11 Q. Well, we were looking at</p> <p>12 "Circumstances that Might Be Indicative of</p> <p>13 Diversion."</p> <p>14 A. Okay.</p> <p>15 Q. And so you would agree that an</p> <p>16 adequate suspicious order monitoring program</p> <p>17 would take into account these four</p> <p>18 circumstances, would it not?</p> <p>19 A. Number 2 I don't think is</p> <p>20 something that would involve what we were in</p> <p>21 the business of doing, ordering a limited</p> <p>22 variety of controlled substances in</p> <p>23 quantities disproportionate to the quantity</p> <p>24 of noncontrolled medications. I -- I</p> <p>25 don't -- I don't see how that applies to us.</p>
<p style="text-align: right;">Page 103</p> <p>1 of that size, okay.</p> <p>2 So if they changed it up and</p> <p>3 they went from a 10 by 50 to a 25 by</p> <p>4 50, you know, just to -- we would --</p> <p>5 we would take the entire amount that</p> <p>6 was being bought, make sure they</p> <p>7 weren't buying more than what they</p> <p>8 normally did.</p> <p>9 So I think we did more so than</p> <p>10 what the regulations were requiring.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. Now, directing your attention</p> <p>13 back to Exhibit 2, do you have that in -- can</p> <p>14 you put that in front of you so that -- yeah,</p> <p>15 that would be the first DEA letter we looked</p> <p>16 at.</p> <p>17 A. Okay.</p> <p>18 Q. And do you see on page 2, it's</p> <p>19 got -- under the "Circumstances that Might Be</p> <p>20 Indicative of Diversion," it's identifying</p> <p>21 four different issues?</p> <p>22 A. Page 2, you said?</p> <p>23 Q. Yes.</p> <p>24 A. And where at?</p> <p>25 Q. "Circumstances that Might Be</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. I'm sorry.</p> <p>2 A. It's not something that we</p> <p>3 would have been looking at.</p> <p>4 Q. Well, isn't that what that --</p> <p>5 well, reading the requirement it says,</p> <p>6 "Ordering a limited variety of controlled</p> <p>7 substances in quantities disproportionate to</p> <p>8 the quantity of noncontrolled medications</p> <p>9 ordered."</p> <p>10 So if a distributor was doing</p> <p>11 that from you, meaning all of the -- well,</p> <p>12 let me rephrase that.</p> <p>13 If a retail pharmacy was only</p> <p>14 ordering controlled substances from you in</p> <p>15 quantities disproportionate to the quantity</p> <p>16 of noncontrolled medications ordered, so</p> <p>17 we're talking a retail pharmacy here --</p> <p>18 A. Okay.</p> <p>19 Q. -- wouldn't that be something</p> <p>20 your suspicious order monitoring program</p> <p>21 should pick up on?</p> <p>22 A. When you say "noncontrolled</p> <p>23 medication orders," I'm not sure,</p> <p>24 noncontrolled medications, what would that</p> <p>25 be?</p>



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1 Q. Well, I assume it would be  
2 other pharmaceuticals that were not, for  
3 example, Schedule II.  
4 A. Okay.  
5 Again, I go back to this is  
6 something that we were not -- we didn't have  
7 the tools to do at that time.  
8 Q. Well, but you would agree that  
9 this is a circumstance that might be  
10 indicative of diversion, would you not?  
11 A. I suppose it could be, yes.  
12 Q. And given that and given that  
13 this is -- I mean, the DEA is flagging this  
14 as an issue that they are concerned about,  
15 wouldn't it be important for Mallinckrodt's  
16 suspicious order monitoring program,  
17 particularly its enhanced SOM program, to  
18 take this into account?  
19 A. We were -- as far as  
20 pharmacies, we were selling to chain  
21 pharmacies and we were shipping to -- to  
22 their shipping sites, not particular  
23 pharmacies. Okay. Not individual  
24 pharmacies. We were selling to their  
25 warehouses.

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1 Q. But if a chain -- if a chain  
2 pharmacy is only ordering Schedule II  
3 substances from you, isn't that something  
4 that your program ought to have taken into  
5 account and registered?  
6 A. If we had the resources to do  
7 so, I suppose so.  
8 MR. TSAI: Dean, this is a time  
9 check. It's been about an hour since  
10 the last break.  
11 MR. KAWAMOTO: Sure. Actually,  
12 why don't I finish up on Exhibit 4 and  
13 then we can take a quick break.  
14 QUESTIONS BY MR. KAWAMOTO:  
15 Q. So page 2 of Exhibit 4, that's  
16 the 2007 DEA letter.  
17 A. Page -- okay.  
18 Q. Page 2.  
19 A. Of 4?  
20 Q. Yes.  
21 It says, "Lastly registrants  
22 that routinely report suspicious orders yet  
23 fill these orders without first determining  
24 that order is not being diverted into other  
25 than legitimate, medical, scientific and

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1 industrial channels may be failing to  
2 maintain effective controls against  
3 diversion."  
4 Now, I guess to use the  
5 Mallinckrodt terminology, I should be  
6 substituting in "peculiar orders"; is that  
7 fair?  
8 A. Correct.  
9 Q. Okay. So registrants that  
10 routinely -- or, you know, registrants that  
11 routinely report peculiar orders yet fill  
12 those orders without first determining that  
13 order is not being diverted into other than  
14 legitimate, scientific and industrial  
15 channels may be failing to maintain effective  
16 controls against diversion.  
17 You would agree with that  
18 statement?  
19 A. Yes.  
20 Q. Okay. So as part of  
21 Mallinckrodt's suspicious order monitoring  
22 program --  
23 A. Yes.  
24 Q. -- it had to make sure that it  
25 did not report -- it did not identify

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1 peculiar orders and yet fill those orders  
2 without first determining that the order was  
3 not being diverted; is that correct?  
4 A. Are you talking about -- at  
5 this time period or are you talking during  
6 when? Are we talking about bulk, or are we  
7 talking about dosage?  
8 Q. Well, let's focus on dosage  
9 products.  
10 A. Okay.  
11 Q. And for dosage products --  
12 A. Right.  
13 Q. -- prior to 2007, it would have  
14 been improper for Mallinckrodt to identify a  
15 peculiar order and fill that order without  
16 first determining that the order was not  
17 being diverted into other than legitimate,  
18 medical, scientific and industrial channels;  
19 is that correct?  
20 A. Yes.  
21 Q. Okay. And presumably in the  
22 post-2007 time period under your enhanced  
23 suspicious order monitoring program, it still  
24 would have been improper to fill an order  
25 without first investigating the order; is



<p style="text-align: right;">Page 110</p> <p>1 that correct?</p> <p>2 MR. TSAI: Object to the form.</p> <p>3 THE WITNESS: Keep it in mind,</p> <p>4 like I've mentioned before, prior to</p> <p>5 2007, we were -- we were instructed by</p> <p>6 our field offices at that time, our</p> <p>7 DEA field offices, that the monthly</p> <p>8 report that we gave them was</p> <p>9 sufficient.</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. But nevertheless, from</p> <p>12 a -- from a standpoint of --</p> <p>13 A. From a -- from -- as far as --</p> <p>14 I can only speak towards bulk because that's</p> <p>15 what I had at the time. Okay.</p> <p>16 So besides the program that we</p> <p>17 had in place, which was what the DEA required</p> <p>18 at that time, regardless of what this letter</p> <p>19 is saying, we were also monitoring our</p> <p>20 customers of any orders that we felt -- our</p> <p>21 CSRs would notify myself or Karen Harper</p> <p>22 that, "Hey, we've got an order that's more --</p> <p>23 more than what the customer normally buys,"</p> <p>24 and we would -- we identify that and turn it</p> <p>25 over to Karen Harper for her -- to discuss</p>	<p style="text-align: right;">Page 112</p> <p>1 A. Yes.</p> <p>2 Q. So with respect to both bulk</p> <p>3 and dosage products, now, with respect to</p> <p>4 both pre-2007 and post-2007, it would have</p> <p>5 been improper for Mallinckrodt to ship an</p> <p>6 order without first concluding an</p> <p>7 investigation -- well, strike that.</p> <p>8 It would have been improper for</p> <p>9 Mallinckrodt to ship a peculiar order without</p> <p>10 first concluding its investigation as to</p> <p>11 whether that order was not going to be</p> <p>12 diverted; is that accurate?</p> <p>13 MR. TSAI: Object to the form.</p> <p>14 THE WITNESS: I would say that</p> <p>15 when I had dosage at the time, that we</p> <p>16 had an agreement with Karen Harper</p> <p>17 that we didn't always have the time</p> <p>18 because orders would go out on a daily</p> <p>19 basis from when they were -- they were</p> <p>20 entered, and they -- if an order</p> <p>21 kicked out as peculiar, we didn't</p> <p>22 always have the ability to do the</p> <p>23 thorough investigation prior to the</p> <p>24 order being shipped. Okay.</p> <p>25 And we came to that conclusion</p>
<p style="text-align: right;">Page 111</p> <p>1 with the DEA.</p> <p>2 I want to keep in mind that in</p> <p>3 the bulk area in a time frame of seven days</p> <p>4 to a month would be our normal period of</p> <p>5 fulfilling an order because we manufactured</p> <p>6 all the orders make-on-order. Okay. We</p> <p>7 didn't stock bulk narcotics. We didn't have</p> <p>8 the -- the inventory to be able to stock it,</p> <p>9 so everything was made to order. And the</p> <p>10 time frame that we needed our -- was anywhere</p> <p>11 from seven days to a month. Okay.</p> <p>12 So we had -- what I'm getting</p> <p>13 at is we had plenty of time prior to the</p> <p>14 order being shipped to determine whether it</p> <p>15 was suspicious order or not.</p> <p>16 Q. Okay. But as I -- as I</p> <p>17 understand this letter to be stating, and</p> <p>18 please correct me if you have a different</p> <p>19 interpretation, what it's saying is that if</p> <p>20 you identify a peculiar order, you should not</p> <p>21 ship that order without investigating whether</p> <p>22 the order is -- whether the order is being</p> <p>23 diverted; is that accurate?</p> <p>24 A. I would say so.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 113</p> <p>1 after several months of orders being</p> <p>2 placed through our system and we did</p> <p>3 not have any suspicious orders. What</p> <p>4 we had -- had any suspicious orders,</p> <p>5 so we felt comfortable that we could</p> <p>6 go ahead and ship the order.</p> <p>7 And the reason why we were not</p> <p>8 able to always thoroughly investigate</p> <p>9 the order prior to it shipping was,</p> <p>10 one, we didn't have the information</p> <p>11 available from the CSR, our first</p> <p>12 contact, okay. They didn't know why</p> <p>13 this is -- this order is being placed</p> <p>14 for -- unusual order was being placed.</p> <p>15 Secondly, we would go to the</p> <p>16 business manager for that product. If</p> <p>17 that business manager didn't know why</p> <p>18 there was an unusual order being</p> <p>19 placed, we would then go to the</p> <p>20 salesperson. This all took time</p> <p>21 because these people aren't always</p> <p>22 available to get back to us. Okay.</p> <p>23 And we felt comfortable enough</p> <p>24 through our -- through this program</p> <p>25 being in place for several months</p>

<p style="text-align: right;">Page 114</p> <p>1 before we went to that that we -- we</p> <p>2 could continue to investigate that</p> <p>3 order because that order was going to</p> <p>4 a distributor who also had a program</p> <p>5 in place for suspicious orders, so we</p> <p>6 knew that we could get the product</p> <p>7 back or stop it if need be.</p> <p>8 QUESTIONS BY MR. KAWAMOTO:</p> <p>9 Q. So in certain circumstances</p> <p>10 then, Mallinckrodt would ship peculiar orders</p> <p>11 without completing its investigation as to</p> <p>12 whether that order might be diverted into</p> <p>13 other than legitimate, medical, scientific or</p> <p>14 industrial channels; is that correct?</p> <p>15 MR. TSAI: Objection. Vague as</p> <p>16 to time.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: Yes, we -- on</p> <p>19 rare circumstances where we didn't</p> <p>20 want to hold up the order because of</p> <p>21 people needing for legitimate reasons,</p> <p>22 medical needs, we didn't want to hold</p> <p>23 up the order, but we continued to go</p> <p>24 through the process of identifying</p> <p>25 whether it was legitimate or not.</p>	<p style="text-align: right;">Page 116</p> <p>1 without their blessing.</p> <p>2 Q. Did Karen Harper ever tell you</p> <p>3 that the DEA had signed off on this</p> <p>4 agreement?</p> <p>5 A. No.</p> <p>6 Q. Okay. And when you say that</p> <p>7 you had an agreement with Karen Harper, what</p> <p>8 do you mean by that?</p> <p>9 A. I asked her, based upon the</p> <p>10 circumstances that I described, if it was</p> <p>11 okay to do this, and she agreed to it.</p> <p>12 Q. Now, was this agreement</p> <p>13 memorialized in writing?</p> <p>14 A. I believe there was an e-mail.</p> <p>15 Q. Okay. Was this agreement</p> <p>16 memorialized in any formal policy put out by</p> <p>17 Mallinckrodt?</p> <p>18 A. Not that I'm aware of.</p> <p>19 Q. So this agreement then would</p> <p>20 not be included in whatever written policy</p> <p>21 you had regarding your enhanced suspicious</p> <p>22 order monitoring program, would it?</p> <p>23 A. I don't remember.</p> <p>24 MR. KAWAMOTO: Okay. Do you</p> <p>25 want to take a break now, Rocky?</p>
<p style="text-align: right;">Page 115</p> <p>1 And I can say that from the</p> <p>2 time period that I have it, we did not</p> <p>3 have a suspicious order.</p> <p>4 QUESTIONS BY MR. KAWAMOTO:</p> <p>5 Q. Did you ever inform DEA that</p> <p>6 you were doing this?</p> <p>7 A. Yes.</p> <p>8 Well, let me say we informed</p> <p>9 our DEA compliance person, Karen Harper, and</p> <p>10 she was in agreement to that.</p> <p>11 Q. But did you ever inform the</p> <p>12 Drug Enforcement Administration?</p> <p>13 A. I did not talk to the Drug</p> <p>14 Enforcement Agency myself.</p> <p>15 Q. Do you know if Karen Harper</p> <p>16 informed the Drug Enforcement Administration?</p> <p>17 A. I don't know what Karen Harper</p> <p>18 did.</p> <p>19 Q. So you have no basis to believe</p> <p>20 that the DEA felt that this was an acceptable</p> <p>21 practice?</p> <p>22 A. I would say, as well as I know</p> <p>23 Karen Harper and how she dealt with the DEA,</p> <p>24 she kept them informed of what we were doing.</p> <p>25 She would not -- she would not do anything</p>	<p style="text-align: right;">Page 117</p> <p>1 MR. TSAI: Let's take a break,</p> <p>2 yeah.</p> <p>3 VIDEOGRAPHER: We're going off</p> <p>4 the record at 11:34 a.m.</p> <p>5 (Off the record at 11:34 a.m.)</p> <p>6 VIDEOGRAPHER: We're back on</p> <p>7 the record at 11:49 a.m.</p> <p>8 QUESTIONS BY MR. KAWAMOTO:</p> <p>9 Q. So, Mr. Rausch, directing you</p> <p>10 to Exhibit 4 again. It's a 2007 DEA letter.</p> <p>11 Do you have that in front of</p> <p>12 you?</p> <p>13 A. Yes.</p> <p>14 Q. So looking on the back page on</p> <p>15 the top paragraph -- and we've discussed this</p> <p>16 briefly during the last session.</p> <p>17 A. Okay.</p> <p>18 Q. Do you see the top paragraph</p> <p>19 where it says, "Registrants that rely on</p> <p>20 rigid formulas to define whether an order is</p> <p>21 suspicious may be failing to detect</p> <p>22 suspicious orders."</p> <p>23 A. Yes.</p> <p>24 Q. And your interpretation of that</p> <p>25 requirement is that you couldn't just rely on</p>

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1 the month before; is that accurate?  
 2 A. Well, I think that's what  
 3 they're -- they're saying here. For example,  
 4 a system that identifies orders as suspicious  
 5 only if the total amount of controlled  
 6 substance ordered during one month exceeds  
 7 the amount ordered the previous month.

8 Q. Okay. And so --

9 A. That -- that I interpret as  
 10 being rigid.

11 Q. And so it would be improper to  
 12 just look at one month, but if you were to  
 13 look at the past two months, that would be  
 14 okay; is that your interpretation?

15 A. No. No.

16 Well, what I'm saying is --  
 17 what we -- what we did is we looked at a  
 18 12-month roving {sic} period of time, as I  
 19 explained earlier, where we not only looked  
 20 at the previous month and the month before  
 21 that and six months before that, but a year's  
 22 basis.

23 So if they placed an order, for  
 24 example, in April, okay, what we looked at  
 25 were orders that had been placed from, say,

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1 March of that year, the month before, through  
 2 the past March of the previous year.

3 And so -- and that -- then that  
 4 just kept changing. If an order was placed  
 5 in May, we would look from April through  
 6 April.

7 Q. Okay.

8 A. Does that make sense?

9 Q. I believe I understand that.

10 A. Okay.

11 Q. I guess my question is so  
 12 your -- your understanding of what it means  
 13 not to rely on a rigid formula is that your  
 14 formula shouldn't be time limited,  
 15 essentially, to one month.

16 Is that -- is that what you're  
 17 indicating?

18 A. I think that's what my -- our  
 19 interpretation is what the DEA is saying  
 20 there. Don't just look at one -- what they  
 21 bought the previous month because that's not  
 22 going to give you a good feel for an order  
 23 pattern that is deviant from possibly past  
 24 orders.

25 Q. And what is your basis for that

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1 interpretation?

2 A. Just thought that was the  
 3 better approach than just looking at one  
 4 month.

5 And if I'm reading here, it  
 6 says, okay, "should not rely on rigid  
 7 formulas to define whether an order is  
 8 suspicious or not," and they give, for  
 9 example, a system that defines -- identifies  
 10 orders as suspicious only in a total amount  
 11 of the controlled substance ordered during  
 12 one month.

13 Q. Well, let me -- go ahead.

14 A. Do I understand what  
 15 you're asking?

16 Q. Well, let me phrase this  
 17 another way.

18 So you have three potential  
 19 options. Option one is you would have -- you  
 20 would base your SOM system on just look --  
 21 just comparing the current order to the  
 22 previous month's order, and your  
 23 understanding is that the DEA disapproved of  
 24 that approach.

25 A. They show that as an example.

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1 Q. The other approach would be,  
 2 you know, what you did -- what Mallinckrodt  
 3 did, which is to compare the current order to  
 4 the average of the past 12 months on a  
 5 rolling basis; is that accurate?

6 A. Correct. Correct.

7 Q. Another approach would be in  
 8 addition to looking at, you know -- in  
 9 addition to comparing the current order to  
 10 the prior 12-month order on a rolling basis,  
 11 you could also look at other factors. For  
 12 example, the factors identified in the 2006  
 13 letter.

14 So, you know, what are -- what  
 15 are they ordering relative -- how much -- or  
 16 how much opioids are they ordering relative  
 17 to other products?

18 Is there -- is there a pattern  
 19 with respect to, you know, how often that  
 20 they are -- they are providing an order that  
 21 would, for example, trigger the peculiar  
 22 order threshold?

23 Are they ordering excessive  
 24 quantities of controlled substances in  
 25 combination with, you know, an excessive

<p style="text-align: right;">Page 122</p> <p>1 quantities of lifestyle drugs?</p> <p>2       So you could have a suspicious</p> <p>3 order monitoring program that had both this</p> <p>4 formula in addition to other factors.</p> <p>5       A.   Well, keep in mind --</p> <p>6       MR. TSAI: Object to the form.</p> <p>7       Go ahead.</p> <p>8       THE WITNESS: Keep in mind that</p> <p>9 as the bulk customer service rep at</p> <p>10 that time, what the DEA -- our field</p> <p>11 office was requiring is what we were</p> <p>12 supplying. We gave them what -- what</p> <p>13 we had as our criteria, which I just</p> <p>14 told you it was based upon a 12-month</p> <p>15 rolling average. They approved that</p> <p>16 and we had that system in place up</p> <p>17 until 2007, 2008, at which time they</p> <p>18 said that was no longer going to be</p> <p>19 valid. And that's when we started</p> <p>20 developing our enhanced program.</p> <p>21       So regardless of what they have</p> <p>22 here, what our requirements were at</p> <p>23 the time was was what I just told you.</p> <p>24 QUESTIONS BY MR. KAWAMOTO:</p> <p>25       Q.   And do you know -- is this the</p>	<p style="text-align: right;">Page 124</p> <p>1 was a particular size, like a 25-tablet</p> <p>2 bottle versus a 50-tablet bottle, they each</p> <p>3 would be separate SKUs. So just not looking</p> <p>4 at the orders for those particular ones. If</p> <p>5 they were within what we called the same</p> <p>6 family, we would look at the total of that</p> <p>7 family.</p> <p>8       So what we wanted to make sure</p> <p>9 as far as diversion is that to keep somebody</p> <p>10 from trying to get something by us is to one</p> <p>11 month order the 50-tab bottle and then the</p> <p>12 next month order the hundred-tab bottle. So</p> <p>13 we were looking at the combined of that</p> <p>14 family, combination of that family, and that</p> <p>15 would be flagged.</p> <p>16       Irregular order patterns was</p> <p>17 added, which I think is talked about in here.</p> <p>18       A number of different things.</p> <p>19       Q.   And I'm sorry, when you were</p> <p>20 talking about the 50 versus a hundred tabs --</p> <p>21       A.   Right.</p> <p>22       Q.   -- what you're referring to</p> <p>23 is --</p> <p>24       A.   Tablet bottles.</p> <p>25       Q.   Tablet bottles.</p>
<p style="text-align: right;">Page 123</p> <p>1 same system that was in place regarding</p> <p>2 dosage products for the prior -- the pre-2007</p> <p>3 time period?</p> <p>4       A.   I believe so, but that's a</p> <p>5 question that I would refer to Cathy Stewart</p> <p>6 who had it at the same time.</p> <p>7       Q.   Okay. And so if I understand</p> <p>8 your testimony, this formula, which was based</p> <p>9 on looking, comparing, the current order to</p> <p>10 the prior 12-month rolling period, that</p> <p>11 formula, was changed after 2007 when you took</p> <p>12 over the role of dosage products?</p> <p>13       A.   Yes.</p> <p>14       Q.   Okay. And what was -- what was</p> <p>15 the change or how was it changed?</p> <p>16       A.   What was our new program?</p> <p>17       Q.   Yes.</p> <p>18       A.   Okay. I don't remember all of</p> <p>19 the particulars, but -- because it's been a</p> <p>20 long period of time.</p> <p>21       With the input of Cathy and</p> <p>22 several other people, it was based upon not</p> <p>23 only the order quantity on a rolling average,</p> <p>24 it was based upon not -- not only on a</p> <p>25 particular SKU, what I'll call a SKU, which</p>	<p style="text-align: right;">Page 125</p> <p>1       So ordering 50 tablet bottles</p> <p>2 from one family and then ordering a hundred</p> <p>3 tablet bottles from another family --</p> <p>4       A.   No, from the same family.</p> <p>5       Okay.</p> <p>6       Q.   Okay.</p> <p>7       A.   So let's say hydrocodone,</p> <p>8 example, let's say they came in sized bottles</p> <p>9 of 50 tablets or a hundred tablets, okay, but</p> <p>10 they all came from the same crude, okay, or</p> <p>11 what we would call family, all right.</p> <p>12       So if somebody came in and</p> <p>13 ordered 100 one month, then came back the</p> <p>14 next month and ordered 50, the computer</p> <p>15 system would keep track of that and look at</p> <p>16 it at the higher level of where that was</p> <p>17 coming from in the crude. It would look at</p> <p>18 the total combination or combined of those</p> <p>19 orders.</p> <p>20       Q.   So it was essentially looking</p> <p>21 at the number of -- it was taking into</p> <p>22 account the number of pills in the dosage --</p> <p>23       A.   Correct.</p> <p>24       Q.   -- as opposed to just --</p> <p>25       A.   Correct.</p>



<p style="text-align: right;">Page 126</p> <p>1 Q. -- you know, how many pills --</p> <p>2 A. Right.</p> <p>3 Q. -- or how many bottles?</p> <p>4 A. Right.</p> <p>5 Q. Okay. So why don't we turn</p> <p>6 to -- I would like to mark as -- I believe</p> <p>7 we're up to Exhibit 5.</p> <p>8 (Mallinckrodt-Rausch Exhibit 5</p> <p>9 marked for identification.)</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. And so I've marked as</p> <p>12 Exhibit 5, it's a PowerPoint. It's dated</p> <p>13 June 5, 2008. Because I've got it printed in</p> <p>14 native form, I'm going to read the Bates</p> <p>15 number into the record. So the Bates number</p> <p>16 for this is MNK-T1_2250046.</p> <p>17 So, Mr. Rausch, I would like</p> <p>18 you to quickly review this PowerPoint and let</p> <p>19 me know when you -- when you're done.</p> <p>20 A. Okay.</p> <p>21 Q. So this is a PowerPoint dated</p> <p>22 June 5, 2008, and its entitled "Introductory</p> <p>23 Training for Field Sales."</p> <p>24 Have you seen this PowerPoint</p> <p>25 before?</p>	<p style="text-align: right;">Page 128</p> <p>1 John Adams didn't.</p> <p>2 Karen Harper, I'm not sure if</p> <p>3 she did or didn't at that time. She -- her</p> <p>4 reporting relationship changed, but I don't</p> <p>5 remember what the time period was.</p> <p>6 Q. Okay. So at one time --</p> <p>7 A. Susan Marlatt didn't.</p> <p>8 Q. At one time she did report to</p> <p>9 JoAnne Levy or --</p> <p>10 A. I don't remember --</p> <p>11 Q. Okay.</p> <p>12 A. -- what her reporting</p> <p>13 relationship was at that time.</p> <p>14 Q. And so in terms of compliance</p> <p>15 issues, the people that would have been</p> <p>16 involved with the compliance side of the</p> <p>17 program -- well, could you identify for the</p> <p>18 people -- for me the people on this team that</p> <p>19 would have been involved in the compliance</p> <p>20 issues?</p> <p>21 A. Well, as far as customer</p> <p>22 service would be myself and Cathy. Susan</p> <p>23 Marlatt from the credit and collections</p> <p>24 department, they would be involved in setting</p> <p>25 up the customer and doing the credit</p>
<p style="text-align: right;">Page 127</p> <p>1 A. I believe I have.</p> <p>2 Q. Okay. Did you help prepare</p> <p>3 this?</p> <p>4 A. No, it was prepared by Karen</p> <p>5 Harper, I believe.</p> <p>6 Q. Okay. But have you reviewed</p> <p>7 this before?</p> <p>8 A. I've seen it before.</p> <p>9 Q. And did you work with Karen</p> <p>10 Harper on preparing this?</p> <p>11 A. No, I don't believe so.</p> <p>12 Q. So turning to page 3 of the</p> <p>13 PowerPoint, it says, "Mallinckrodt's</p> <p>14 suspicious order procedure team."</p> <p>15 A. Oh, okay.</p> <p>16 Q. Do you see that page?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Who is JoAnne Levy or Levy?</p> <p>19 A. JoAnne Levy is the -- was the</p> <p>20 VP of logistics.</p> <p>21 Q. So did everyone else report up</p> <p>22 to her?</p> <p>23 A. No. Bill -- let's see.</p> <p>24 Michael Pheney did. I did.</p> <p>25 Cathy did. Bill Ratliff, I believe, did.</p>	<p style="text-align: right;">Page 129</p> <p>1 background checks on them.</p> <p>2 Who else we got?</p> <p>3 We all reported into -- well,</p> <p>4 not all. Cathy and myself reported into</p> <p>5 Michael Pheney.</p> <p>6 Kimberly France, I don't</p> <p>7 remember her.</p> <p>8 Q. And who was responsible for</p> <p>9 making sure that the program and the policies</p> <p>10 complied with the DEA regulations and</p> <p>11 applicable law?</p> <p>12 A. That would be Karen Harper.</p> <p>13 Q. Okay. Now, there are team</p> <p>14 advisors listed at the bottom of the page.</p> <p>15 A. Right.</p> <p>16 Q. Do you know what role they</p> <p>17 played?</p> <p>18 A. Their role was to enforce what</p> <p>19 the order monitoring procedures became --</p> <p>20 rolled out. They were at a higher level.</p> <p>21 This presentation was given and Jerry Moss</p> <p>22 was the vice president of sales for the bulk</p> <p>23 division, and Jason Jones, I'm not sure, but</p> <p>24 he was over one of the sales organizations.</p> <p>25 And same with Jeff Burd, he was marketing.</p>

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1 Bob Lesnak was in sales over the methadone  
2 area, I believe, and then Eileen Spaulding,  
3 was -- again, she reported into Karen Harper.

4 Q. And so you indicated that their  
5 role was to enforce what the monitoring  
6 procedure.

7 So they -- did they help  
8 develop them or -- sorry?

9 A. Well, when I -- when you say  
10 "enforce," to make sure that this was rolled  
11 out to our salespeople.

12 And what happened here, what  
13 occurred, was every year the sales force  
14 would get together for a week-long period of  
15 time to go over different things that were  
16 going on in sales and then something like  
17 this would be rolled out by Karen during that  
18 week --

19 Q. Okay.

20 A. -- just to instruct them on  
21 what the new DEA regulations -- what the DEA  
22 regulations were, what we were doing as far  
23 as developing a new program, what their role  
24 was expected of them in this program, and so  
25 forth.

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1 Q. And so the person that would  
2 have been responsible for making sure that  
3 the suspicious order monitoring program  
4 complied with the DEA requirements was Karen  
5 Harper?

6 A. She would be the -- yes.

7 Q. And so she would have been the  
8 one that spoke to the DEA about this program?

9 A. She probably tried -- yeah, she  
10 would notify them, but the DEA did not say  
11 one way or the other whether they liked it or  
12 they didn't approve it or disapprove it.  
13 They -- they stayed out of that.

14 Q. Okay.

15 A. As far as I remember.

16 Q. Now, did --

17 A. They didn't recommend a program  
18 and didn't say whether -- or approve programs  
19 as far as I know.

20 Q. But if they had concerns, they  
21 would let Mallinckrodt know, wouldn't they?

22 A. Oh, yes. Yes.

23 Q. Did this team have team  
24 meetings?

25 A. Yes.

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1 Q. And did someone take notes at  
2 those meetings?

3 A. I don't remember. I don't  
4 remember.

5 Q. Was there any type of secretary  
6 for these meetings?

7 A. No.

8 Q. Did this team have any central  
9 files?

10 A. I don't remember.

11 Most of the teams -- in this --  
12 I don't see -- let's see.

13 Everybody was given assignments  
14 on what was needed to be done and we work on  
15 our assignments and meet on a frequent basis  
16 to see where we were as far as coming up with  
17 the new suspicious order reporting system.

18 Q. And who was the team leader?

19 A. I believe it was Karen.

20 Q. So she would have been the one  
21 giving out assignments and making sure that  
22 they were completed; is that correct?

23 A. Well, she wouldn't give out  
24 assignments. During the meeting, we would  
25 all talk about what we wanted to see, and

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1 based upon what person was involved in that  
2 particular area, they would go back and work  
3 on that.

4 Say for IT, we asked them to  
5 take a look at -- "IT" meaning information  
6 services or computer people, okay -- we would  
7 ask them to see, you know, can this be  
8 implemented into the system, so they would go  
9 back and do their due diligence on whether  
10 that can be done.

11 Cathy and I would be -- would  
12 take a look at, you know, what was possible  
13 on our end to get done.

14 So everybody was given  
15 assignments and then we would come back and  
16 talk about what we had come up with or done.

17 Q. And so -- well, strike that.

18 Do you know when this team was  
19 first formed?

20 A. Not the exact time frame. This  
21 was probably June of 2008. Probably earlier  
22 in that time frame since we kind of details  
23 out a little bit what we're going to be  
24 looking at. Probably early 2008, maybe late  
25 2007.

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1 Q. And was this team in existence  
2 for your entire time between 2008 and 2013?

3 A. No, this was just to roll out  
4 our new order monitoring system. What --  
5 I -- I had control -- I had part of the  
6 suspicious order monitoring program until  
7 fall of 2010. Then it was turned over to  
8 another group.

9 Q. Okay.

10 A. As far as being the one that  
11 would follow up on peculiar orders and that.

12 Q. And in fall of 2010, do you  
13 know who it was turned over to?

14 A. Tiffany -- I don't see her name  
15 here. I do not remember her last name.

16 Q. And was she in a different  
17 group?

18 A. She was.

19 Q. What group was she in?

20 A. I believe chargebacks.

21 Q. So if you turn to the next  
22 page, page 4, it says, "DEA policy on  
23 suspicious orders."

24 A. Okay.

25 Q. And one of the bullet points

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1 is, "Registrant is reminded that the  
2 responsibility does not end merely with the  
3 filing of suspicious order report."

4 A. Correct.

5 Q. What does that mean to you?

6 A. That's referring to the report  
7 that we were sending on a monthly basis.

8 Q. And so what are your additional  
9 responsibilities other than filing -- well,  
10 strike that.

11 What are the responsibilities  
12 you have after filing your suspicious order  
13 report?

14 A. Well, not only after filing it,  
15 but during the interim, remember this was a  
16 month-to-month report that we filed and it  
17 was at the end of the month. So during a  
18 month our -- our responsibilities were to  
19 continue to look at the orders independent of  
20 a report to see if there was unusual order  
21 activity or -- or unusual orders being placed  
22 that were out of the norm for that particular  
23 customer.

24 As I talked about earlier this  
25 morning, on the bulk side, our CSRs had a

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1 good feel who our customers were. We dealt  
2 with them for years. And there wasn't that  
3 many distributors in that that were -- or  
4 drug manufacturers at that time. So we had a  
5 pretty good idea of what their order patterns  
6 were and that.

7 And so if we felt something was  
8 unusual or whatever, we would bring that up  
9 to the business manager for the product  
10 and/or the salesperson.

11 Q. And when did you become -- when  
12 did you -- when were you placed in charge of  
13 the dosage products?

14 A. 2008.

15 Q. 2008.

16 So --

17 A. Fall of 2008, I believe.

18 Q. So would have been after this  
19 presentation, but --

20 A. Yes.

21 Q. A couple months after?

22 A. Yes.

23 Q. And so with respect to this  
24 bullet point and your responsibilities on the  
25 dosage side of Mallinckrodt's business, what

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1 additional responsibilities did you have  
2 other than filing the suspicious order  
3 report?

4 A. On the bulk side?

5 Q. No, on the dosage side.

6 A. Oh, at that time I did not have  
7 any responsibilities. I'm sorry.

8 Q. Well, this -- you've got a  
9 bullet point here that says, "Registrant is  
10 reminded that their responsibility does not  
11 end merely with the filing of suspicious  
12 order report."

13 A. This is Cathy -- this would be  
14 Cathy Stewart's responsibility.

15 Q. Understood.

16 But this requirement would also  
17 have applied to you when you took over the  
18 dosage side of the business, correct?

19 A. After our -- after our new  
20 reporting system was put in place.

21 Q. So what additional  
22 responsibilities -- after the new reporting  
23 system gets put in place --

24 A. Okay.

25 Q. -- what additional

Page 138

1 responsibilities did you have other than  
2 filing the suspicious order report?  
3 A. We no longer file that report.  
4 Our new monitoring system took the place of  
5 that. The DEA didn't -- no longer wanted us  
6 to send that report.

7 So during the time period of  
8 2000 -- late 2008 and 2009, we worked on  
9 our -- and this is discussed in this  
10 presentation -- this team that was put  
11 together worked on coming up with a new  
12 report.

13 My responsibilities after it  
14 was put in place was to receive the daily  
15 reports, peculiar order reports, that flagged  
16 the orders that were out of the log  
17 rhythms {sic} of the normal order patterning.  
18 Okay.

19 And my job, which I think I  
20 kind of discussed earlier, was to -- the  
21 orders that were flagged was to then talk to  
22 the CSRs, the business managers, and the  
23 sales force that were involved with this  
24 particular customer that we were selling to  
25 and trying to explain why the order pattern

Page 139

1 was not being followed or why this was an  
2 unusual or peculiar order.

3 Q. And so -- well, so when did  
4 this enhanced SOM policy become effective?

5 A. I believe it was in the fall  
6 of 2009 is when we put it in place. This was  
7 after -- after months of working on what we  
8 wanted to see in the report. This is after  
9 we tested -- put it in a test mode and ran it  
10 parallel with our order entry system to see  
11 if there was anything kicking out that  
12 shouldn't been, and then we put it in what I  
13 call live production.

14 Q. And so prior to 2009, what  
15 policy and procedures were in place regarding  
16 dosage products?

17 A. So just our normal due  
18 diligence of the DEA requirements of making  
19 sure that we had the 222 forms prior to the  
20 order being shipped. All orders were placed  
21 on hold prior to that form being received.  
22 So that was our policy.

23 Q. And you -- did you have any  
24 policy or process in place to identify  
25 suspicious dosage orders between the fall

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1 of 2008 and the fall of 2009?

2 A. As I discussed, just our normal  
3 DEA compliance with the 222 forms and that.  
4 We were working on the process.

5 Other than the CSRs bringing up  
6 a suspicious order based upon their  
7 knowledge, we did not have a -- a suspicious  
8 order program in place at that time as we  
9 developed it.

10 Q. So in -- let's say we're  
11 talking January of 2009 here.

12 A. Okay.

13 Q. A manufacturer -- I'm sorry, a  
14 distributor for the dosage products submits  
15 an order that is, say, more than two times  
16 what it requested the prior month, that would  
17 not have been flagged for further review or  
18 investigation?

19 A. If the CSR noticed that it was  
20 a larger order than normal based upon past  
21 history, which we had on our computer, they  
22 would bring it to the attention of -- of the  
23 salesperson or the business manager for  
24 approval to ship it.

25 Q. And was there a threshold that

Page 141

1 was being applied, or how was the CSR to know  
2 that this was an unusual, large order?

3 A. Just from past order history  
4 that was on the sales -- on the computer.

5 Q. And so any order that was  
6 larger than the past sales history, or did it  
7 have to be larger by a certain amount?

8 A. There wasn't a formal program  
9 in process. As this -- as this suspicious  
10 order thing points out, we were in the  
11 process of coming up with a new program, so  
12 from that standpoint, we didn't have a -- a  
13 computer system that was doing it. It was  
14 just informal.

15 Q. So I just want to make sure I  
16 understand the chronology here.

17 So prior to 2008, for the  
18 dosage products, what was the formula that  
19 was applied to determine if there were -- if  
20 an order was suspicious or not?

21 A. Prior to 2008, to my -- best of  
22 my knowledge, because I was in the bulk area,  
23 they were reporting the best -- or the same  
24 way that I was, which was a monthly report.

25 Q. And that is they would look at



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1 the current month's report -- I'm sorry, they  
2 would look at the current order and compare  
3 it to the prior month?

4 A. Rolling 12 months.

5 Q. On a rolling 12-month basis.

6 And what was the threshold that  
7 would trigger it being viewed as suspicious?

8 A. The average of that 12-month.  
9 Two times that.

10 Q. Two times that.

11 Okay. So prior to 2008, on the  
12 dosage -- sorry.

13 A. Let me -- let me qualify that.

14 I was not over that program at  
15 the time. I was not in dosage, but I believe  
16 that's what they were using, but I can't say  
17 for sure. That question should be asked of  
18 Cathy Stewart.

19 Q. Understood.

20 But to the best of your  
21 knowledge, prior to 2008, the formula that  
22 was in place regarding dosage products was  
23 that you looked at the current order and  
24 compared it to the 12-month rolling average,  
25 and if that order was more than two times the

Page 143

1 12-month rolling average, that would be  
2 flagged as a peculiar order?

3 A. I'm assuming that's what they  
4 were doing.

5 Q. Okay.

6 A. That's what we did on the bulk  
7 side.

8 Q. And then in 2000 -- late 2008,  
9 when you assumed control of the dosage  
10 products --

11 A. Uh-huh. After the -- after the  
12 program was -- the new --

13 Q. After the program was --

14 A. Was put in place.

15 Q. -- was put in place, but before  
16 the new formula was developed, you didn't  
17 have a formula in place at all?

18 A. Correct.

19 Q. So you just got rid of the --  
20 you no longer looked at the comparison  
21 between the current order and the 12-month  
22 rolling -- the two month -- I'm sorry?

23 A. The DEA asked us to discontinue  
24 sending them that letter.

25 Q. Well, I understand that the DEA

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1 had asked -- had asked you to discontinue  
2 sending them the report.

3 But did they also tell you that  
4 you didn't need to look at that data anymore?

5 A. I don't remember.

6 Q. But nevertheless, that -- that  
7 formula was discontinued, and until fall  
8 of 2009, nothing replaced it; is that  
9 correct?

10 MR. TSAI: Object to the form.

11 THE WITNESS: That's correct.

12 QUESTIONS BY MR. KAWAMOTO:

13 Q. So between the fall of 2008 and  
14 the fall of 2009, your regulatory system  
15 was -- well, strike that.

16 Between the fall of 2008 and  
17 the fall of 2009, the only regulatory -- the  
18 only regulatory requirement that you had in  
19 place to guard against diversion for dosage  
20 products was the 222 forms?

21 MR. TSAI: Object to the form.

22 THE WITNESS: You say -- when  
23 you say "only," it was the -- part of  
24 the DEA requirement program that we  
25 have 222 forms and quota forms

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1 required that, and to make -- to say  
2 "only" kind of, I think, minimizes  
3 or -- is playing it down that it was  
4 not an important part of the DEA  
5 regulations. We still had that  
6 requirement.

7 And keep in mind, we were -- we  
8 were shipping to distributors who also  
9 had requirements on having programs in  
10 place. We were not shipping to the --  
11 the end users. There was many layers  
12 of other players in this -- in this --  
13 I shouldn't say players, but other  
14 people or companies that were involved  
15 in the suspicious order process  
16 besides Mallinckrodt.

17 So to say, yes, we did not have  
18 a program in place at the time. The  
19 DEA was well aware that we did not  
20 have a suspicious order program in  
21 place. They asked us to put one in  
22 place, and we kept them informed --  
23 and when I say "we," Karen Harper,  
24 kept them informed -- on the progress  
25 of developing the new program, and to

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1 my knowledge, they were fine with  
2 that.  
3 QUESTIONS BY MR. KAWAMOTO:  
4 Q. But nevertheless, if you were  
5 to compare January of 2008 with January  
6 of 2009, the regulatory requirements in  
7 effect on January of 2009 would be less than  
8 the regulatory effects in January of -- than  
9 the regulatory requirements for January  
10 of 2008, that's correct?

11 MR. TSAI: Object to the form.

12 THE WITNESS: I would have to  
13 agree, yes.

14 QUESTIONS BY MR. KAWAMOTO:

15 Q. Okay. Why was it important to  
16 have -- strike that.

17 With respect to the  
18 pre-enhanced SOM program, you know -- well,  
19 strike that.

20 Why did Mallinckrodt have this  
21 12-month rolling -- this [REDACTED]  
22 [REDACTED] in place?  
23 What was its purpose?

24 A. The DEA asked us to report on a  
25 monthly basis to them suspicious orders, what

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1 they called suspicious order, to develop a --  
2 a program, which I described to you, and to  
3 send that to them on a monthly basis.

4 Q. And this was in addition to the  
5 222 form requirement, correct?

6 A. The quota form, yes.

7 Q. Yes.

8 So why -- what was the benefit  
9 of this added regulatory requirement given  
10 that you had the quota form in place?

11 A. I can't answer that. That's  
12 a -- that's a question that you would have to  
13 ask the DEA or Karen Harper.

14 Q. But you would agree that this  
15 was --

16 A. This was what was asked of us.  
17 We came up with a formula, and I think you  
18 can even see the -- that we submitted to them  
19 and they approved as far as the monthly  
20 reporting basis, and that's what we went  
21 with.

22 MR. KAWAMOTO: Well, so it's  
23 12:30 now, Rocky. Do you want to take  
24 a break for lunch?

25 MR. TSAI: That's okay.

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1 MR. KAWAMOTO: Do you want to  
2 come back at 1:15, 1:30?

3 MR. TSAI: Let's do 45 minutes.  
4 Is that okay?

5 THE WITNESS: Good.

6 VIDEOGRAPHER: We're going off  
7 the record at 12:28 p.m.

8 (Off the record at 12:28 p.m.)

9 VIDEOGRAPHER: We're back on  
10 the record at 1:19 p.m.

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. So, Mr. Rausch, in terms of the  
13 bulk product side of the business, in 2007,  
14 were you aware that Purdue pleaded guilty  
15 with respect to its opioid business in  
16 federal court?

17 A. No, I'm not.

18 Q. So were you aware that the  
19 government was conducting an investigation  
20 into Purdue?

21 A. I don't remember that.

22 Q. Okay. And you don't have any  
23 knowledge or awareness or any recollection of  
24 the fact that, for example, the Purdue  
25 general counsel entered a guilty plea in

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1 connection with that investigation?

2 A. I don't have recollection of  
3 that, no.

4 Q. Now, in terms of screening your  
5 customers on the bulk side of the business,  
6 is that information that you would take --  
7 you would have wanted to take into account in  
8 determining whether or not to ship your  
9 products to them?

10 MR. TSAI: Object to the form.

11 THE WITNESS: I would say, yes,  
12 probably, it would be. Yes.

13 QUESTIONS BY MR. KAWAMOTO:

14 Q. Okay.

15 A. If they were -- if they were --  
16 was their license suspended; do you know?

17 Q. I don't believe there was a  
18 license suspension. I think it was a -- it  
19 was a criminal indictment relating to  
20 their -- to aspects of their business.

21 A. Okay. Oh.

22 And what was your question,  
23 again?

24 Q. Well, is this information -- in  
25 terms of screening your customers -- well,

<p style="text-align: right;">Page 150</p> <p>1 strike that.</p> <p>2 You would agree that it is</p> <p>3 important for Mallinckrodt to screen its</p> <p>4 customers?</p> <p>5 A. I agree.</p> <p>6 Q. And part of that screening</p> <p>7 should involve taking into account, you know,</p> <p>8 whether they have any regulatory violations,</p> <p>9 whether there are any pending investigations,</p> <p>10 by the DOJ, the DOA or a state Attorney</p> <p>11 General; is that fair?</p> <p>12 A. We would continue to monitor</p> <p>13 the orders that were being placed by them,</p> <p>14 and if Karen Harper informed us that we were</p> <p>15 not supposed to ship it to them anymore, even</p> <p>16 though you mentioned that they did not have</p> <p>17 their license suspended or whatever, I think</p> <p>18 unless we were informed otherwise, we</p> <p>19 probably would continue our order processing,</p> <p>20 monitoring as it was then.</p> <p>21 Q. So was the -- was the license</p> <p>22 suspension the only reason Mallinckrodt would</p> <p>23 stop shipping products to a customer?</p> <p>24 A. I'm trying to think if there's</p> <p>25 other reasons that I can think of offhand.</p>	<p style="text-align: right;">Page 152</p> <p>1 order monitoring, and it says, "Revision</p> <p>2 number draft 3, published 6/02/2008."</p> <p>3 A. Okay.</p> <p>4 Q. So would this document have</p> <p>5 been prepared in connection with the</p> <p>6 suspicious order monitoring team and your</p> <p>7 enhanced SOM?</p> <p>8 A. Yes, it seems to be in the same</p> <p>9 time period that we were working on it.</p> <p>10 Q. Okay. And do you know if this</p> <p>11 document was ever finalized?</p> <p>12 A. I don't remember.</p> <p>13 Q. Was there a written document</p> <p>14 that memorialized Mallinckrodt's enhanced</p> <p>15 suspicious order monitoring program?</p> <p>16 A. I don't remember.</p> <p>17 Q. So if I were to -- let's say in</p> <p>18 2014, if I were to be hired by Mallinckrodt</p> <p>19 to oversee its enhanced suspicious order</p> <p>20 monitoring program with respect to dosage</p> <p>21 products and I were to ask to see what the</p> <p>22 policy was, what would you -- what would you</p> <p>23 give to me?</p> <p>24 MR. TSAI: Object to the form.</p> <p>25 THE WITNESS: In 2014?</p>
<p style="text-align: right;">Page 151</p> <p>1 If Karen wanted us to stop for</p> <p>2 whatever reason, other than license</p> <p>3 suspension, she would inform us to do so, and</p> <p>4 I don't remember if she did or not.</p> <p>5 Q. And do you have any -- do you</p> <p>6 recall -- strike that.</p> <p>7 Do you have any recollection of</p> <p>8 Karen asking you to stop shipment for someone</p> <p>9 for a reason other than a license suspension?</p> <p>10 A. I don't recall.</p> <p>11 (Mallinckrodt-Rausch Exhibit 6</p> <p>12 marked for identification.)</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. So I would like to mark this as</p> <p>15 Exhibit 6.</p> <p>16 And it is -- it bears the Bates</p> <p>17 number MNK-T1_419993. It's Exhibit 6.</p> <p>18 So, Mr. Rausch, have you seen</p> <p>19 this document before?</p> <p>20 A. I don't remember it.</p> <p>21 Q. Okay.</p> <p>22 A. That doesn't mean I didn't see</p> <p>23 it, but I don't remember it.</p> <p>24 Q. And this is a DEA compliance</p> <p>25 procedure, controlled substance suspicious</p>	<p style="text-align: right;">Page 153</p> <p>1 QUESTIONS BY MR. KAWAMOTO:</p> <p>2 Q. Yes.</p> <p>3 A. I didn't work for the company</p> <p>4 in 2014.</p> <p>5 Q. Well, fair enough.</p> <p>6 In 2013, if I'm coming in as</p> <p>7 your replacement --</p> <p>8 A. Right.</p> <p>9 Q. -- to oversee the dosage</p> <p>10 products, and I ask -- and my responsibility</p> <p>11 is to oversee --</p> <p>12 A. Right.</p> <p>13 Q. -- the enhanced suspicious</p> <p>14 order monitoring program, what document would</p> <p>15 you have provided to me?</p> <p>16 A. Most likely it would have a</p> <p>17 document like this, because we did have -- we</p> <p>18 did have documents for how things work at</p> <p>19 customer service, and I am sure we had</p> <p>20 something -- I would guess that we did have</p> <p>21 something in place similar to this on what</p> <p>22 customer service would do as far as the</p> <p>23 procedure.</p> <p>24 Q. Okay. So turning to page 2 of</p> <p>25 this -- of this draft policy?</p>

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1 A. Okay.

2 Q. Do you see the section entitled

3 "Credit Department"?

4 A. I do.

5 Q. And it says, "Performs Dun &

6 Bradstreet and/or other information checks on

7 new controlled substance customers to

8 determine credit worthiness."

9 Was this part of the enhanced

10 SOM program for dosage products?

11 A. I'm not -- I'm not sure if it's

12 part of the enhanced. I'm not sure what the

13 credit department did prior to this period of

14 time, but I know they did -- they did check

15 Dun & Bradstreet to -- prior to the new

16 program.

17 I would say the -- the part

18 about referring the new customer account to

19 the director of DEA compliance would be new,

20 and the conducts periodic checks for existing

21 accounts would also be new.

22 Q. And I guess in terms of sort of

23 overall what I'm trying to accomplish, I'm

24 trying to understand whether or not these

25 components made it into the final version of

Page 155

1 the enhanced SOM program.

2 So with respect to the enhanced

3 SOM program or the final version, would the

4 credit department have performed a Dun &

5 Bradstreet --

6 A. Yes.

7 Q. -- check?

8 A. Yes.

9 Q. Okay.

10 A. I didn't work in that

11 department, but I'm sure that that was part

12 of their -- their process going forward.

13 Q. And what was the purpose of

14 performing that review or asking Dun &

15 Bradstreet to perform that review?

16 A. It would just give them a

17 history of -- credit history of sales and

18 that type of thing, if they had, you know,

19 any debt or had gone bankrupt or that type of

20 thing. I'm not speaking as a credit person,

21 but I think that's what that was part of it.

22 Q. So this would have addressed

23 the concern -- I mean, the concern that

24 Mallinckrodt had about the financial solvency

25 of the institution --

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1 A. Correct.

2 Q. -- and presumably whether it

3 would be able to pay any debts it owed to

4 Mallinckrodt, correct?

5 A. Correct.

6 Q. Would this have helped prevent

7 diversion in any way?

8 A. No, I think this is -- this is

9 just a -- part of the credit department's

10 ongoing procedure.

11 Like I said, it was probably

12 two and three of this credit department that

13 you have here that would be new to the

14 compliance, SOM, suspicious order.

15 Q. When you say "two or three,"

16 what do you mean?

17 A. Sentences two or three under

18 the credit department.

19 Q. Okay. So just so I'm clear,

20 Dun & Bradstreet was not related to diversion

21 control?

22 A. No, that was always a -- a

23 check that they did prior to -- to putting in

24 a new customer.

25 Q. Okay. And so Section 2 is --

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1 refers to the new account customer DEA

2 compliance of the new account has no

3 historical or financial information available

4 or if the data shows liens, lawsuits or other

5 information which might raise suspicions to

6 the legitimacy of the new account company.

7 And how does that help

8 prevent -- or how does that assist in

9 diversion control?

10 A. Well, again, you're speaking

11 about an area that I was not part of, okay,

12 so I can't answer that question. That's a

13 credit department question.

14 Q. And so the credit -- well, you

15 indicated that part of your responsibilities

16 was you identified -- part of your

17 responsibilities under the enhanced SOM

18 program is that you would identify peculiar

19 orders or they would be identified to you on

20 a report; is that fair?

21 A. That's correct.

22 Q. And then you would then take

23 that order and interact with various people

24 in the sales department to determine if there

25 was a basis for that order; is that correct?



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1 A. Correct.

2 Q. Did you ever interact with the  
3 credit department to determine if there was a  
4 basis for the order?

5 A. This is referring to new  
6 customer accounts, okay. So the order would  
7 never -- there would never be an order placed  
8 unless the credit department established them  
9 as a -- as a new customer. Okay. So that  
10 would be preliminary work to me ever  
11 receiving an order.

12 Q. And was there any effort made  
13 to update this information?

14 A. There was a yearly -- there was  
15 a yearly form that was sent out by the credit  
16 department from what I can remember, that  
17 they had to -- it was a checklist that they  
18 had to fill out and send back to the credit  
19 department to keep their account current, and  
20 it had questions concerning the compliance  
21 that we were doing for the suspicious order  
22 monitoring program.

23 This wasn't something new that  
24 was developed. I can't speak to what was all  
25 involved, but there was a yearly report or

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1 checklist that was sent out to the customer  
2 and they had to fill it out and send it back  
3 to them to keep them current as the customer.

4 Q. Okay. And this was -- this was  
5 all being -- this was being done in  
6 connection with --

7 A. Our enhanced reporting system  
8 and suspicious order reporting.

9 Q. Okay. But credit didn't have  
10 any role in reviewing individual orders?

11 A. No.

12 Q. Okay. Now, the next section is  
13 on field sales.

14 And by "field sales," I assume  
15 we're referring to the -- the salespeople in  
16 the field?

17 A. Correct.

18 Q. Okay. It says, "Completes site  
19 survey checklist for new controlled substance  
20 customers," and then "conducts an on-site  
21 visit, including taking photographs inside  
22 and out for review by security director and  
23 DEA compliance manager."

24 A. Uh-huh.

25 Q. Do you know what the purpose of

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1 the on-site visit and the photographs were?

2 A. The reason for that is take a  
3 look at the physical property itself to see  
4 if it looked like a legitimate business.  
5 They didn't want it to be running out of  
6 somebody's house or whatever, so it had to be  
7 like, you know, physically have to look like  
8 there's a company that you would want to sell  
9 to and not being run out of back -- back of a  
10 hotel or something like that.

11 So this information was passed  
12 on to the DEA director, I believe, is --  
13 yeah, it's security.

14 Q. And your -- this requirement  
15 applies to Mallinckrodt's customers, correct?

16 A. Yes.

17 Q. Would it be your expectation  
18 that the distributors would be doing  
19 something similar for their customers?

20 A. I -- I can't answer that.

21 Q. From a standpoint of diversion  
22 control, do you think it would be important  
23 for a distributor to do this?

24 MS. YOCUM: Objection. Form.

25 THE WITNESS: I can't speculate

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1 on what they -- what we -- they would  
2 feel is important.

3 Everybody had their own  
4 program, okay. We didn't have any  
5 guidelines from the DEA on what our  
6 program should look like.

7 So as far as what the other  
8 companies or distributors did as far  
9 as their program, I don't -- I can't  
10 answer that.

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. Well, I understand that you --  
13 sorry.

14 A. Well, to answer that, you're  
15 asking me would I feel that that would be  
16 something that they would want to do?

17 Q. Yes.

18 A. I would say yes.

19 Q. Now, for the customer service  
20 representatives, they break this up into bulk  
21 narcotics and dosage customer service reps.

22 Do you see that?

23 A. I do.

24 Q. And so you would have been  
25 responsible for the dosage customer service

<p style="text-align: right;">Page 162</p> <p>1 representative section; is that fair?</p> <p>2 A. At that time, I was -- fall</p> <p>3 of 2008.</p> <p>4 Q. Okay.</p> <p>5 A. So kind of in a transit year,</p> <p>6 but eventually, yes, I become manager --</p> <p>7 manager over the dosage area.</p> <p>8 Q. Okay. And on the top of --</p> <p>9 well, at the bottom of page 2 of 5 and going</p> <p>10 on to page 3 of 5, do you see, "Dosage</p> <p>11 customer service representatives will perform</p> <p>12 the following activities"?</p> <p>13 A. I'm sorry, which one am I</p> <p>14 supposed to be looking at?</p> <p>15 Q. At the bottom of page 2 of 5.</p> <p>16 So at the bottom of 41994. Under "Dosage</p> <p>17 Customer Service Representatives."</p> <p>18 A. Okay. Page 3?</p> <p>19 Q. Yes.</p> <p>20 A. Okay.</p> <p>21 Q. No, I'm sorry, page 2 of 5.</p> <p>22 A. Okay. Under the "bulk"</p> <p>23 section?</p> <p>24 Q. Under the "dosage." So beneath</p> <p>25 "bulk."</p>	<p style="text-align: right;">Page 164</p> <p>1 it says, "Need clarification."</p> <p>2 And again, this -- it does say</p> <p>3 draft, so this is a working document that was</p> <p>4 not the final document.</p> <p>5 Q. And so -- and that's part of</p> <p>6 why I'm asking these questions. I want to</p> <p>7 see if these -- if these responsibilities</p> <p>8 were transferred or were put into the final</p> <p>9 policy.</p> <p>10 A. Okay.</p> <p>11 Q. But the first one is, "Verify</p> <p>12 that the customer has a valid DEA</p> <p>13 registration certificate."</p> <p>14 I assume that was part of the</p> <p>15 final policy?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Then it also says,</p> <p>18 "Ensure that the customer has provided a</p> <p>19 properly executed DEA 222 form for C-I and</p> <p>20 C-II substances."</p> <p>21 A. Correct.</p> <p>22 Q. Was that part of the final</p> <p>23 policy?</p> <p>24 A. Yes.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 163</p> <p>1 A. Okay. This is page 2.</p> <p>2 Q. Uh-huh.</p> <p>3 A. And this is page 3.</p> <p>4 Q. So page 2 would be this section</p> <p>5 right here.</p> <p>6 A. Oh, okay. Under --</p> <p>7 Q. So it says, "Dosage customer</p> <p>8 service representatives."</p> <p>9 A. Okay. Okay.</p> <p>10 Q. Okay. And it has -- it lists</p> <p>11 various requirements that start on page 2 and</p> <p>12 follow on to page 3.</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 I didn't -- I haven't read it</p> <p>16 yet, though.</p> <p>17 Q. Okay.</p> <p>18 A. Do you want me to read it?</p> <p>19 Q. Yes, please.</p> <p>20 A. Okay.</p> <p>21 This looks like a working</p> <p>22 document from what I can see, because I can</p> <p>23 see there's some -- there's some questions</p> <p>24 here where it says, "Dosage customer service</p> <p>25 will perform the following activities," and</p>	<p style="text-align: right;">Page 165</p> <p>1 A. That was part of our policy</p> <p>2 before the -- this program, but, yes, go</p> <p>3 ahead.</p> <p>4 Q. And then it also says, "Flag</p> <p>5 orders that deviate from the norms in terms</p> <p>6 of quantity order, frequency of order and/or</p> <p>7 pattern of normal order placement. CSRs will</p> <p>8 evaluate the circumstances of the order.</p> <p>9 This evaluation should be based on their</p> <p>10 knowledge of the specific customer and the</p> <p>11 industry in which the customer operates, and</p> <p>12 should the circumstances deviate from the</p> <p>13 norm, upon completion of the order, place</p> <p>14 same on hold and notify security and customer</p> <p>15 service manager."</p> <p>16 A. Okay.</p> <p>17 Q. Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Was that part of the final</p> <p>20 policy?</p> <p>21 A. That was part of our ongoing</p> <p>22 policy. Okay.</p> <p>23 So as I talked while we were --</p> <p>24 before where we were discussing what was --</p> <p>25 what took place, why we're developing our</p>

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1 final policy, this is the type of thing --  
 2 type of thing I was talking about where the  
 3 CSR was, you know, knew the customer best and  
 4 was to keep us informed if they saw something  
 5 that was being ordered that was different  
 6 from normal.  
 7 Q. And how was the CSR to  
 8 determine whether something was different  
 9 from normal?  
 10 A. Just from their knowledge of  
 11 the customer, like I discussed earlier. Now,  
 12 if they --  
 13 Q. I'm sorry. Go ahead.  
 14 A. Yeah, because this is referring  
 15 not -- this is -- okay. This is -- we're  
 16 looking at bulk here. Dosage is over here.  
 17 Yeah, "This evaluation should  
 18 be based on their knowledge of the specific  
 19 customer and the industry in which the  
 20 customer operates, and should the  
 21 circumstances deviate from the norm, upon  
 22 completion of the order, place same on hold  
 23 and notify security," which would be Karen  
 24 Harper's group, "and customer service  
 25 manager."

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1 Q. And so was this --  
 2 A. That was in place while we were  
 3 developing our program, and also as -- as we  
 4 went on, our program would kick out these  
 5 orders, so the CSRs still had the chance, as  
 6 they were placing the order, to say, "Hey,  
 7 something's wrong here," and bring it to the  
 8 attention of the customer service manager or  
 9 the DEA compliance officer, but we also had  
 10 our program in place that would flag orders  
 11 that were considered peculiar.  
 12 Q. And that program in place to  
 13 flag orders, that was what was activated in  
 14 the fall of 2009?  
 15 A. That's correct.  
 16 Q. So with respect to the ability  
 17 of the CSR to identify orders that they think  
 18 are peculiar, were there standards they were  
 19 supposed to apply in that respect?  
 20 A. Just -- just orders that  
 21 were -- seemed out of place to them.  
 22 Q. Okay.  
 23 A. As far as I remember.  
 24 Q. And how many different CSRs did  
 25 you have?

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1 A. I think there were five.  
 2 Q. So you have five CSRs.  
 3 A. Right.  
 4 And they were -- they were  
 5 responsible for particular customers.  
 6 Q. Okay. And the CSRs were part  
 7 of the sales team, were they not?  
 8 A. No. They reported into  
 9 logistics.  
 10 Q. Yeah.  
 11 And so how were the CSRs  
 12 compensated?  
 13 A. They weren't under the bonus  
 14 program. They just had a salary.  
 15 Q. So they didn't have a bonus  
 16 program; it was just a salary?  
 17 A. Yes.  
 18 Q. Okay. And in terms of the  
 19 factors that a CSR was to consider in  
 20 determining whether an order was peculiar,  
 21 was there a list of factors?  
 22 A. I'm sorry, say that again.  
 23 Q. Let me rephrase that question.  
 24 So as I understand it, the CSR  
 25 had the ability to flag an order that he or

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1 she believed was peculiar or unusual; is that  
 2 fair?  
 3 A. For that customer, yes.  
 4 Q. Okay. And in terms of  
 5 assessing whether an order was peculiar or  
 6 unusual, was there a set of -- was there a  
 7 written standard that they were supposed to  
 8 apply or a set of factors they were supposed  
 9 to look to?  
 10 A. Just past order history for  
 11 that customer, and then they would talk to --  
 12 bring it to my attention or to the business  
 13 manager and ask them if they knew why this  
 14 particular order was different from what  
 15 their normal order pattern was, and then  
 16 if -- go ahead.  
 17 Q. And in terms of past order  
 18 history, what we're talking about is just  
 19 looking at whatever -- whatever they had --  
 20 whatever they had ordered previously?  
 21 A. Correct.  
 22 Q. And was there any threshold  
 23 that was applied in terms of, you know, an  
 24 order X percentage above the prior history  
 25 would be viewed as peculiar, or was it really

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1 left up to the CSR?

2 A. I don't remember, to be honest

3 with you, what -- what we gave them as

4 parameters, whether it was an X factor or if

5 it's just based upon their -- their knowledge

6 and the order history during this time period

7 while we were developing our suspicious order

8 program.

9 Q. And did you have any program in

10 place to audit the CSRs to make sure that

11 they were -- they were accurately picking up

12 on suspicious orders?

13 A. Not that I remember.

14 Q. Were CSRs evaluated on their

15 ability to properly identify suspicious

16 orders?

17 A. Were they evaluated?

18 Q. Well, let me -- let me rephrase

19 that question.

20 The CSRs were subject to an

21 annual review process, correct?

22 A. That's correct.

23 Q. Was part of this annual review

24 process a review of, you know, whether they

25 accurately identified suspicious orders?

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1 MR. TSAI: Object to the form.

2 THE WITNESS: Not that I

3 remember.

4 QUESTIONS BY MR. KAWAMOTO:

5 Q. So do you have any way of

6 ascertaining whether or not the CSRs

7 successfully identified suspicious orders?

8 A. Well, I just -- I just want to

9 point out not only were our customer service

10 reps and Mallinckrodt responsible for

11 identifying suspicious orders, but also the

12 people that we sold to, which were the

13 distributors, and the distributors to the

14 pharmacies all were responsible for doing

15 this.

16 So as far as diversion and that

17 type of thing, there was -- there was a long

18 list of people in between us and the customer

19 or the end user.

20 Q. Mallinckrodt had a number of

21 different distributors that it did business

22 with, correct?

23 A. That's correct.

24 Q. Do you know if any of these

25 distributors ever had their licenses revoked

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1 by the DEA?

2 A. If they did -- and I don't want

3 to say I remember that any particular one

4 was, but I believe that there was, but I

5 couldn't tell you who it was, and if it was

6 the DEA would notify us and then we would no

7 longer sell to them. But I can't say yes or

8 no for sure that there was a -- a distributor

9 who was -- had their license suspended.

10 Q. Well, based on your -- your

11 reading or your viewing of news reports, are

12 you aware of distributors that appear to have

13 been abusing the system?

14 A. In 2008?

15 Q. Well, in 2008 up till 2017.

16 A. I think there was, yes.

17 Q. Okay. And, you know, is it

18 fair to say that these distributors were not

19 properly applying whatever standards they

20 were supposed to prevent diversion?

21 MS. YOCUM: Objection. Form.

22 QUESTIONS BY MR. KAWAMOTO:

23 Q. So you can answer.

24 A. Oh, okay.

25 That's -- that's speculation on

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1 my point. I don't know.

2 Q. Was it consistent with your

3 understanding of Mallinckrodt's

4 responsibilities with respect to the DEA

5 rules and regulations that Mallinckrodt could

6 rely on the distributors to do their job to

7 stop diversion, or were you independently

8 responsible for preventing suspicious orders?

9 A. I believe that we were

10 responsible for monitoring our customers and

11 that's what we were working on at the time.

12 Q. And so if your customers were

13 improperly distributing Mallinckrodt

14 products, then these Mallinckrodt products

15 would contribute to the diversion crisis,

16 wouldn't they?

17 MR. TSAI: Object to the form.

18 MS. YOCUM: Object to the form.

19 THE WITNESS: That's possible.

20 QUESTIONS BY MR. KAWAMOTO:

21 Q. Well, it's more than possible;

22 it's likely, sir, isn't it?

23 MR. TSAI: Object to the form.

24 THE WITNESS: If you say so.

25



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1 QUESTIONS BY MR. KAWAMOTO:  
 2 Q. So going back to this document,  
 3 I think it's Exhibit 6 --  
 4 A. Exhibit 6?  
 5 Q. Yes.  
 6 We were looking at page --  
 7 A. Okay.  
 8 Q. -- 3 of 5.  
 9 A. Uh-huh.  
 10 Q. In terms of -- there's a  
 11 paragraph here that says, "If the dosage  
 12 customer service representatives are  
 13 contacted by a new customer asking that a  
 14 account be set up and the interview process  
 15 yields questionable results, the CSR will  
 16 obtain the following information from the  
 17 customer and forward that information in an  
 18 e-mail to the director of security as well as  
 19 the customer service manager."  
 20 Do you see that?  
 21 A. I do.  
 22 Q. And was that part of the  
 23 enhanced SOM program?  
 24 A. I believe so.  
 25 Q. And do you recall this ever

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1 occurring?  
 2 A. Again, if -- this was a working  
 3 document, and if -- this probably would have  
 4 went to the director of security, and if he  
 5 felt that we should not set them up, we  
 6 probably would not.  
 7 Q. Okay. But do you recall any  
 8 instances where the director of security  
 9 declined to set up an account because of  
 10 concerns about the interview process?  
 11 A. No. I don't recall that.  
 12 Q. And this -- this -- this  
 13 paragraph references both the director of the  
 14 security as well as the customer service  
 15 manager.  
 16 A. Right.  
 17 Q. Do you see that?  
 18 A. Uh-huh.  
 19 Q. And that would have been you  
 20 for dosage products in the 2008 to 2013 time  
 21 period?  
 22 A. Going forward, it would have  
 23 been me.  
 24 Q. Okay. Do you recall ever  
 25 receiving reports from the customers -- from

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1 customer service representatives about  
 2 questionable customers?  
 3 A. I don't remember.  
 4 Q. And so during the five years  
 5 that you were the customer service manager  
 6 for dosage products, you don't recall ever  
 7 receiving a customer service report  
 8 recommending that an account not be set up;  
 9 is that fair?  
 10 A. I don't remember, yes.  
 11 I don't know if that was part  
 12 of the final -- how a draft the final -- this  
 13 is the draft. I don't know if that was the  
 14 final product or not.  
 15 Q. Okay. So going down to the  
 16 next section, which is "Customer Service  
 17 Manager."  
 18 A. Uh-huh.  
 19 Q. It says -- well, actually, can  
 20 you review that section?  
 21 A. Okay.  
 22 Q. So it references a peculiar  
 23 order daily report.  
 24 Was this part of the enhanced  
 25 SOM program?

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1 A. It was proposed. I don't think  
 2 it ever went into effect.  
 3 Q. Okay. So did you -- did you  
 4 ultimately receive a report of suspicious  
 5 orders?  
 6 A. Yes. In August when we  
 7 finalized --  
 8 Q. Finalized the program?  
 9 A. -- the program, yes.  
 10 Q. In what way was that report  
 11 different than the peculiar order daily  
 12 report that's described here?  
 13 A. There was more information that  
 14 was used for determining whether an order was  
 15 peculiar than what is outlined here.  
 16 Q. Okay. And what was the  
 17 additional information that was used?  
 18 A. Yeah, like I mentioned before,  
 19 it's got unusual large, unusual frequency and  
 20 our deviation quantity to establish order  
 21 pattern.  
 22 From what I remember, it also  
 23 looked at that -- that family that I talked  
 24 about where if they ordered 50 pills, as you  
 25 described it, and now they ordered 100 pills,

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1 it would look -- would be looking at the  
2 total, not just that particular SKU. So that  
3 was added into it.

4 And I believe there's some  
5 other factors that would -- that were put  
6 into the -- into the program other than it  
7 was just outlined here.

8 Q. Okay. And going back to the  
9 family point that you had.

10 A. Uh-huh.

11 Q. Is this a difference between  
12 looking at orders on a SKU basis versus an  
13 API basis? Is that one way to think of this?

14 A. Yeah. Yes.

15 Q. And so what is an API?

16 A. Well, API is an active  
17 pharmaceutical ingredient.

18 Q. And what is --

19 A. Essentially what that is is  
20 that API is the active ingredient in a -- in  
21 a -- let's use a tablet, for instance. To  
22 make a tablet, you can't just make it from  
23 the active ingredient. There's other  
24 chemicals that have to be added to it so it  
25 can be pressed into a tablet. Okay. That

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1 had no chemical or no -- how do I want to say  
2 it? It did nothing for the patient, okay,  
3 that had nothing to do with it. It was just  
4 how to format a pill or that. So that would  
5 be the inactive ingredients in a tablet.

6 Does that make sense?

7 Q. I believe I understand.

8 I guess -- well, let me ask you  
9 this.

10 A. So let me better explain it.

11 Q. Okay.

12 A. Okay. We made -- say we wanted  
13 to make hydrocodone, okay. That was the  
14 active ingredient in the tablet.

15 To that, we would add compac,  
16 which is acetaminophen that was compressible.  
17 Okay. So those two would be added together,  
18 and they would be put in pill presses and  
19 make the product, the end product.

20 But the inactive ingredient had  
21 no benefit to the -- or could -- did not have  
22 any drug ingredient in it.

23 Q. And so what is the -- what is  
24 the diversion benefit of looking at the API  
25 as opposed to the SKU? Or let me rephrase

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1 that.

2 What is the concern you have  
3 with respect to looking at a SKU that is  
4 fixed if you look at the API?

5 That's what I'm trying to  
6 understand.

7 A. Okay. So if you had 5 --  
8 5 milligrams in a tablet and -- one tablet  
9 and you had 10 milligrams in another tablet,  
10 you would want to look at the total for that  
11 particular -- the API of that particular  
12 product. Okay.

13 So if a customer ordered  
14 10 milligrams of that family, say  
15 hydrocodone, and then decided, "Well, I  
16 ordered too many of those, I'm going to order  
17 5 milligrams of that active ingredient" -- to  
18 keep from the orders looking like they were  
19 heavy, they could order one and one, one and  
20 one, and it wouldn't trigger the two times or  
21 whatever of the suspicious order program.  
22 It's a way around the infrequent -- not  
23 infrequent, but, you know, twice the amount  
24 of a particular order.

25 Follow me?

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1 Did I explain that well enough  
2 for you?

3 Q. Well, I'm still trying to  
4 understand this. I guess let me -- let me  
5 ask it this way then.

6 A. All right.

7 Q. What is -- what is the problem  
8 by just looking at the prior order history on  
9 a SKU basis? What -- if you were to do that,  
10 what are you missing?

11 A. On a SKU basis?

12 Q. Yes.

13 A. Okay.

14 Q. How could you game the system  
15 if it was based on a SKU basis as opposed to  
16 the API basis?

17 A. Okay. If I ordered, let's say,  
18 on a SKU basis, a hundred tablets of this one  
19 SKU, okay, then another SKU of the same  
20 product, okay, had a different number of  
21 tablets. Okay. If I ordered a hundred and  
22 then I went over to the other one and I  
23 ordered a hundred of that, okay, it would get  
24 under that -- that frequency of, say, if I  
25 ordered twice as many as normal of the

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1 hundred.  
 2 Q. Okay.  
 3 A. Or twice as many of the 50. So  
 4 if I split it up and ordered one and one,  
 5 okay, it wouldn't hit that threshold, okay.  
 6 They're ordering twice as many of the  
 7 hundreds as they normally do, if they bounce  
 8 back and forth.  
 9 Does that make sense?  
 10 Q. Okay. I think I understand.  
 11 And would it solve this problem  
 12 if you were to look at it on a SKU-by-SKU  
 13 basis or --  
 14 A. I don't understand your  
 15 question, to solve this problem.  
 16 Q. Actually, I'll withdraw that  
 17 question. I think I understand what you're  
 18 getting at.  
 19 Okay. And so other than  
 20 looking at essentially -- well, strike that.  
 21 So with respect to the peculiar  
 22 order report that you were receiving, in  
 23 addition to the information regarding size,  
 24 frequency and order pattern, it also took  
 25 into account the family of drugs, I guess, or

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1 they looked at things on an API basis.  
 2 A. Right.  
 3 Q. Were there other factors as  
 4 well?  
 5 A. There were, but I don't  
 6 remember all of them.  
 7 Q. Now, do you see the reference  
 8 to a do-not-ship list?  
 9 A. Yes.  
 10 Q. Was that part of the enhanced  
 11 SOM program?  
 12 A. Yes. What would -- well, it  
 13 was an ongoing -- I mean, Karen Harper would  
 14 get a report from the DEA of -- of customers  
 15 or other than customers that were potential  
 16 customers from the DEA that we were not to be  
 17 shipping to any -- it's kind of a warning  
 18 list, do not ship to these customers or  
 19 whatever.  
 20 And then what we would do is  
 21 flag -- if it was an existing customer, we  
 22 would flag that customer so that we could not  
 23 accept any orders into the system for that  
 24 customer.  
 25 Q. So this -- this do-not-ship

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1 list was entirely dependent on the DEA  
 2 saying, "Don't ship to this person"; is that  
 3 fair?  
 4 A. Yes.  
 5 Well, no. That we determine as  
 6 part of the program of suspicious activity.  
 7 So if we had found a customer  
 8 that was a suspicious order, we had said was  
 9 a suspicious order, and we could not verify  
 10 that it was a good order, then there was  
 11 flags in the system created that would flag  
 12 that customer that we could not accept one of  
 13 their -- their orders. That was part -- that  
 14 was part of the new program.  
 15 Q. And so --  
 16 A. Along with what the DEA sent  
 17 out.  
 18 Q. So just so I understand, there  
 19 are two ways to get on this list: One of  
 20 them would be the DEA would put them on the  
 21 list.  
 22 A. Right.  
 23 Q. The other way would be  
 24 Mallinckrodt would independently determine  
 25 based on the orders they're submitting that

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1 they -- that they are -- you know, their  
 2 orders are problematic or that there are  
 3 diversion concerns --  
 4 A. Yes.  
 5 Q. -- and put them on this list.  
 6 A. Yes.  
 7 Q. Okay. Who maintained this  
 8 list?  
 9 A. It was maintained in our order  
 10 entry system, and customer service -- or -- I  
 11 believe that customer service was in charge  
 12 of that, if it ever occurred.  
 13 Q. Okay. Do you recall how many  
 14 entities were put on this list in the 2008  
 15 through 2013 time period?  
 16 A. We did not have any suspicious  
 17 orders at that time, during that time period.  
 18 Q. So is it fair to say then that  
 19 no one was on this do-not-ship list?  
 20 A. Through the monitoring program.  
 21 Q. Okay. So the only entities  
 22 that were put on this list then were from  
 23 DEA?  
 24 A. At that time, yes.  
 25 Q. Then do you see at the very

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1 bottom of the page --  
 2 A. Proposed preliminary dosage.  
 3 Q. Yeah, proposed preliminary  
 4 dosage formula, and then it follows on the  
 5 following page as to what that formula is.  
 6 A. And that's what I was trying to  
 7 explain to you where it says add purchase  
 8 quantities by product, all oxy products and  
 9 again by individual SKUs. Okay. So it's  
 10 looking at the -- the API also.  
 11 Okay.  
 12 Q. And so --  
 13 A. It's pretty detailed.  
 14 Q. So does this -- is this formula  
 15 an accurate depiction of the formula that was  
 16 applied to dosage products for the 2008  
 17 through 2013 time period?  
 18 A. Not 2008. I think this was  
 19 in --  
 20 Q. Sorry, my apologies.  
 21 A. 2000 --  
 22 Q. From fall of 2009 until 2013,  
 23 is this the formula that was applied to  
 24 dosage products?  
 25 A. I believe that's -- again, this

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1 was a work-in-progress draft, but I believe  
 2 that this was part of that end product.  
 3 Q. So looking at the end  
 4 program --  
 5 A. Uh-huh.  
 6 Q. -- what was the formula applied  
 7 to dosage products from fall of 2009  
 8 through 2013? Can you tell me --  
 9 A. What was the formula?  
 10 Q. Yes, what was the formula.  
 11 A. Well, it's written out here  
 12 exactly what the formula consisted of.  
 13 Q. So for --  
 14 A. It's pretty complicated, so for  
 15 me to verbally tell you, I don't know if I --  
 16 if I could describe it well enough.  
 17 Q. Well --  
 18 A. It looked --  
 19 Q. Sorry.  
 20 A. It looked at order quantity --  
 21 there was just a number of them that I don't  
 22 remember all the formula. I couldn't spell  
 23 it out -- spiel it out for you anymore.  
 24 Q. Well, if we look at the  
 25 pre-2007 formula, it was looking at -- it was

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1 taking the current order and comparing it to  
 2 the rolling 12-month --  
 3 A. Right.  
 4 Q. I'll strike that.  
 5 It was taking the current -- it  
 6 was taking the current order and comparing it  
 7 to the rolling 12-month average times [REDACTED]; is  
 8 that accurate?  
 9 A. Correct. Uh-huh.  
 10 Q. And so this new formula was  
 11 comparing the current order to a rolling  
 12 12-month average times [REDACTED], isn't that the  
 13 factor for -- if there's a factor that  
 14 says -- it says factor Schedule II controlled  
 15 substances?  
 16 A. Well, that -- that along with  
 17 some other things that are also here.  
 18 Customers will multiply -- with multiple  
 19 ship-to locations should have their total  
 20 aggregated at the sold-to level but also  
 21 reviewed at the ship-to level. Okay.  
 22 So it was not only looking at  
 23 the individual -- it was looking at just not  
 24 the individual distributors, but it was  
 25 looking at the total that that distributor

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1 was purchasing.  
 2 Had customer months for every  
 3 record used in the above total month within  
 4 the last -- customer center. Went down to  
 5 zero.  
 6 So okay. It's just writing --  
 7 this is just writing out the formula of how  
 8 it should be done.  
 9 So you take that information,  
 10 you divide the total quantity purchased by  
 11 total customer months, then multiply -- okay,  
 12 I'm sorry, what was your -- what were you  
 13 going to say?  
 14 Q. Well, looking -- I'm trying to  
 15 understand the difference between the  
 16 pre-2007 formula, which was for dosage  
 17 products a rolling 12-month average times  
 18 [REDACTED] --  
 19 A. Okay.  
 20 Q. -- and the formula under the  
 21 enhanced SOM program.  
 22 A. Okay. This is one part of the  
 23 formula -- this is a formula right here of  
 24 what it should look like. It also looked at  
 25 your regular order patterns, okay. It looked



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1 at, like I said, at the family, or the API,  
2 which we didn't look at pre-2009. The  
3 pre-2009 just looked at the order by double,  
4 okay.

5 So I think I've said three  
6 things already that the other -- that the  
7 original report that we sent to the DEA on a  
8 monthly basis did not have.

9 And I don't think this is the  
10 final version. It had even more.

11 Q. And in terms of how this  
12 formula was -- well, strike that.

13 How was this formula applied to  
14 Mallinckrodt orders?

15 A. Okay. So this was -- this was  
16 put in in our order entry system, and on a --  
17 on a daily basis all orders were compared to  
18 the log rhythms {sic} that we had set in  
19 place for our customers and orders.

20 If there was anything that did  
21 not fit the normal order pattern or what we  
22 would consider the normal order pattern based  
23 upon our guidelines and what we had put in  
24 place, it would flag that order and a report  
25 would print out that I looked at on a daily

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1 basis.

2 And it would show me the orders  
3 that had been flagged as peculiar. And as  
4 discussed earlier, I would take -- is that  
5 what you're looking for?

6 Q. Yes.

7 A. Okay.

8 Q. And how would it -- how  
9 would -- how would the program tell whether  
10 an order did not fit the normal order  
11 pattern?

12 A. Based upon these formulas that  
13 were put into the system.

14 Q. But what -- I mean, what  
15 specifically was this formula supposed to  
16 take into account? What specifically was the  
17 formula looking for in determining what a  
18 normal order pattern was and what a deviation  
19 from that was?

20 A. If it was -- if it didn't meet  
21 the criteria of the formulas that -- that we  
22 had put in place as far as -- for example,  
23 twice the orders in a rolling 12-month  
24 period, it would kick out. That's just one  
25 example. Okay.

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1 Another example is if it was,  
2 say, they hadn't ordered for two or three  
3 months and then all of a sudden we received a  
4 large order from a customer, that would be  
5 considered an irregular order pattern. Okay.  
6 That would kick out on this report.

7 Again, I -- I talk about the  
8 API. If their total API for an order was  
9 greater than whatever the criteria was for  
10 that, it would kick out.

11 Those were reasons for the  
12 order to kick out on the report.

13 Q. And where -- was this formula  
14 written down somewhere?

15 A. I believe what we put into the  
16 computer was probably written down somewhere.  
17 I don't remember exactly.

18 This was given to our  
19 information services people that were on the  
20 team and it was put into their systems, so it  
21 was probably -- it was documented by them.

22 Q. Okay. And did you work with  
23 anyone in particular in the information  
24 services team?

25 A. I believe it was on the --

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1 let's see.

2 I don't see any of the people  
3 listed from IS on this team that -- this  
4 report here, but there were -- I don't -- I  
5 don't remember the people's names that were  
6 from -- I remember Steve, but I don't  
7 remember his last name.

8 So they were -- they were part  
9 of the team and they were brought in when we  
10 came -- came to a point where we were ready  
11 to give them some -- give them information  
12 that we wanted implemented into the computer  
13 system, and we would have to write up a  
14 document spelling out exactly what it was  
15 that we wanted to be put into the system.

16 Q. And did you write up this  
17 document, or did someone else write it?

18 A. Someone else wrote it up. I  
19 don't remember who exactly.

20 Q. Do you -- and you don't recall  
21 who?

22 A. No.

23 Q. Okay. And what -- you  
24 referenced an IS computer system.

25 Did that system have a name?

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1 A. That -- that would be our order  
2 entry system.  
3 Q. So the order entry system, was  
4 that the JD Edwards system?  
5 A. Yes.  
6 Q. And so as part of the computer  
7 code in this JD Edwards system, you would  
8 have this formula that got applied to all of  
9 the orders?  
10 A. That's correct.  
11 Q. Okay. And so if an order  
12 wasn't flagged by application of this  
13 algorithm, that order didn't get examined or  
14 looked at; is that correct?  
15 A. That's correct.  
16 Q. Okay. So if your -- if your  
17 algorithm was faulty or had a gap or was  
18 missing something, then, you know,  
19 potentially orders that were problematic  
20 could get through; is that fair?  
21 MR. TSAI: Objection.  
22 THE WITNESS: That's a  
23 possibility.  
24 QUESTIONS BY MR. KAWAMOTO:  
25 Q. In other words, your suspicious

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1 order -- your enhanced suspicious order  
2 monitoring program was, you know, only as  
3 good or as bad as this algorithm was; is that  
4 fair?  
5 A. That would be --  
6 MR. TSAI: Object as to form.  
7 QUESTIONS BY MR. KAWAMOTO:  
8 Q. And who was -- other than you,  
9 who helped develop this algorithm?  
10 A. Everybody on the team was --  
11 had input on what they felt, and that was  
12 part of the -- the team that was put together  
13 to work on what we felt should be in the --  
14 in the order entry -- what we should put in  
15 the order entry system or this suspicious  
16 order program.  
17 So Cathy Stewart, Sue Marlatt  
18 was probably involved in it, myself, Karen  
19 Harper, and, like I said, IT would probably  
20 have -- would have had somebody in there at  
21 the point where we would need them as far as  
22 advising us what was possible.  
23 And then we would write up the  
24 document that we wanted to have put into the  
25 system and submit that to IT for

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1 implementation, testing and so forth.  
2 Q. And do you recall a memo ever  
3 being drafted that would lay out this  
4 algorithm and how it worked, or was it just  
5 computer code that was put into the computer  
6 program?  
7 A. There was probably a document.  
8 I don't know -- I don't remember where the  
9 document -- if -- who had it, but the  
10 document had to be developed to give to IT.  
11 They had a -- they had a form that had to be  
12 filled out and submitted to them for  
13 evaluation and coding and amount of resources  
14 needed and time needed to do the  
15 implementation.  
16 Q. And do you recall -- did this  
17 form have a name?  
18 A. I don't recall.  
19 (Mallinckrodt-Rausch Exhibit 7  
20 marked for identification.)  
21 QUESTIONS BY MR. KAWAMOTO:  
22 Q. Okay. So I would like to mark  
23 as Exhibit 7 another document. It bears a  
24 Bates number MNK-T1\_477900.  
25 So if you could take a minute

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1 to review this document and let me know when  
2 you're done.  
3 And I have -- I mean, it's a  
4 relatively lengthy document, so I have, you  
5 know, specific questions relating to certain  
6 portions of it.  
7 A. Do you want me to read all of  
8 it?  
9 Q. No.  
10 Have you read the first half?  
11 A. Yes, I've --  
12 Q. Okay.  
13 A. -- scanned through it, yes.  
14 Q. So have you ever seen this  
15 document before?  
16 A. I don't remember it.  
17 Q. Okay. Now, is my understanding  
18 correct that this document is, to some  
19 extent, a chronology or a timeline of the  
20 development of the enhanced suspicious order  
21 monitoring program?  
22 A. It looks like it, yes.  
23 Q. Okay. And at the very top it  
24 says, "Activities 08/2008 through 08/2010."  
25 Do you see that?

<p style="text-align: right;">Page 198</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And the suspicious --</p> <p>3 the enhanced suspicious order monitoring</p> <p>4 program with its revised algorithm launched</p> <p>5 in the fall of 2009; is that correct?</p> <p>6 A. Correct.</p> <p>7 Q. Okay.</p> <p>8 A. Oh, Robyn McHale was the person</p> <p>9 that -- from IT that worked on it. She was a</p> <p>10 freelance IT person.</p> <p>11 You know what that is, right?</p> <p>12 Q. Actually, I don't. I'm sorry.</p> <p>13 A. Okay. It's a person that</p> <p>14 worked independently for themselves and then</p> <p>15 we would hire them to do work for us.</p> <p>16 Q. Essentially like a consultant;</p> <p>17 is that fair?</p> <p>18 A. Yeah, that would be a name for</p> <p>19 it.</p> <p>20 Q. And did she have a -- did she</p> <p>21 have a Mallinckrodt e-mail, a Mallinckrodt</p> <p>22 account?</p> <p>23 A. At that time she probably did,</p> <p>24 but I don't know if she still works with</p> <p>25 Mallinckrodt or not.</p>	<p style="text-align: right;">Page 200</p> <p>1 A. The IS department, I would say,</p> <p>2 would have that.</p> <p>3 Q. Okay. Okay. So directing your</p> <p>4 attention to page 2 of this timeline.</p> <p>5 A. Okay.</p> <p>6 Q. Do you see there's an entry</p> <p>7 involving you, it's 03/02/2009?</p> <p>8 A. Okay.</p> <p>9 Q. And it says, "Jim Rausch</p> <p>10 continues work with IS to define the criteria</p> <p>11 of what would be a peculiar order and how to</p> <p>12 determine programmatic flags for detection."</p> <p>13 Is that accurate?</p> <p>14 A. Yes.</p> <p>15 Let me explain this. I was --</p> <p>16 at the time I was fairly new to dosage, and</p> <p>17 Cathy was fairly new to bulk, so she was</p> <p>18 working with the dosage log rhythms {sic} and</p> <p>19 I was working on the bulk, because she had</p> <p>20 more experience on the dosage side.</p> <p>21 Q. And then it says, "CSR</p> <p>22 managers," that would have been you and</p> <p>23 Cathy?</p> <p>24 A. Where are we at?</p> <p>25 Q. The entry below that?</p>
<p style="text-align: right;">Page 199</p> <p>1 Q. Do you know if she had an</p> <p>2 office at Mallinckrodt?</p> <p>3 A. She had a cubicle, yes. I</p> <p>4 believe she did. Either -- at times she</p> <p>5 worked from her home, too, but -- I think she</p> <p>6 did, but I don't remember anymore.</p> <p>7 Q. Okay. And she would have been</p> <p>8 the person --</p> <p>9 A. She was one of the people that</p> <p>10 I remember from IS that was working on</p> <p>11 implementing this into the JD Edwards system.</p> <p>12 Q. And so she would likely have</p> <p>13 the document that set out what the exact</p> <p>14 algorithm was?</p> <p>15 A. She could be, but I would say</p> <p>16 that would -- probably since she was a</p> <p>17 consultant, she would not be the person that</p> <p>18 would -- that would have it now. It would</p> <p>19 probably reside with somebody in IT that</p> <p>20 actually worked for Mallinckrodt.</p> <p>21 Q. Okay. And that person would</p> <p>22 likely have the -- not only the enhanced</p> <p>23 suspicious order monitoring algorithm as of</p> <p>24 2009, but all the variations of it up until</p> <p>25 present; is that correct?</p>	<p style="text-align: right;">Page 201</p> <p>1 A. Oh.</p> <p>2 Q. "The CSR managers begin review</p> <p>3 of customer segmentation categories within</p> <p>4 the order entry system to determine if</p> <p>5 separate algorithms to define peculiar order</p> <p>6 patterns will be necessary based on a class</p> <p>7 of trade."</p> <p>8 A. Correct.</p> <p>9 Q. Do you know what the final</p> <p>10 determination of that was?</p> <p>11 A. That we probably would have</p> <p>12 separate needs depending on our customers.</p> <p>13 Q. So this means that you would</p> <p>14 have separate algorithms depending on the</p> <p>15 class of customer?</p> <p>16 A. What it means is based upon our</p> <p>17 business needs, okay. What we did for dosage</p> <p>18 may be different from what we do for bulk as</p> <p>19 far as what we implemented.</p> <p>20 Q. Okay. But within the dosage</p> <p>21 algorithm --</p> <p>22 A. Yeah.</p> <p>23 Q. -- it was not further</p> <p>24 subdivided into different classes of</p> <p>25 customers?</p>

<p style="text-align: right;">Page 202</p> <p>1 A. No.</p> <p>2 Q. So you had one -- you had</p> <p>3 one -- for dosage products, you had one</p> <p>4 algorithm that was applied to wholesalers,</p> <p>5 distributors, retail pharmacies?</p> <p>6 A. Correct.</p> <p>7 Q. The same algorithm?</p> <p>8 A. If I remember. Again, I didn't</p> <p>9 develop, but I believe so.</p> <p>10 Q. Okay. And then do you see</p> <p>11 6/29/2009, it says, "Revised customer</p> <p>12 questionnaires are submitted to legal that</p> <p>13 have been updated based upon CSR focus group</p> <p>14 meetings Jim Rausch and Cathy Stewart</p> <p>15 conducted with CSRs"?</p> <p>16 A. Yes, I see that. Okay.</p> <p>17 Q. What is that in reference to?</p> <p>18 A. It was a questionnaire that I</p> <p>19 think we worked on, but I'm not sure if we</p> <p>20 ever did -- what it composed of. I don't</p> <p>21 remember it.</p> <p>22 Q. And so are you not sure whether</p> <p>23 it was ultimately ever sent out?</p> <p>24 A. Correct. I'm not sure what we</p> <p>25 did with that.</p>	<p style="text-align: right;">Page 204</p> <p>1 through the top e-mail, can we take a</p> <p>2 break?</p> <p>3 MR. KAWAMOTO: Sure.</p> <p>4 THE WITNESS: Okay. So this</p> <p>5 was an e-mail -- or this was what I</p> <p>6 believe -- oh, okay. It is from</p> <p>7 Cathy.</p> <p>8 Cathy, like I said, was working</p> <p>9 on the formulas for the dosage</p> <p>10 business, and I think this was --</p> <p>11 somebody says -- this doesn't make</p> <p>12 sense.</p> <p>13 E-mails from Cathy. I'm</p> <p>14 getting confused.</p> <p>15 I'm not sure if that's Karen</p> <p>16 that's saying that, but --</p> <p>17 QUESTIONS BY MR. KAWAMOTO:</p> <p>18 Q. Well, the top line says, "work</p> <p>19 continues with IS on algorithms, e-mail</p> <p>20 follows from Cathy Stewart."</p> <p>21 A. Right.</p> <p>22 Q. And it -- that seems to</p> <p>23 indicate that Cathy Stewart is saying --</p> <p>24 A. Okay. Cathy Stewart sent an</p> <p>25 e-mail to Robyn. "I'm sorry to ask this</p>
<p style="text-align: right;">Page 203</p> <p>1 Q. And it says, "CSR focus group</p> <p>2 meetings."</p> <p>3 What -- do you recall what the</p> <p>4 focus group meetings were?</p> <p>5 A. No, I don't.</p> <p>6 Q. Okay. Now, it says 7/2009,</p> <p>7 "CDIG begin sending out SM customer</p> <p>8 questionnaires."</p> <p>9 What is "CDIG"?</p> <p>10 A. Customer data integrity group.</p> <p>11 Q. And you don't know whether they</p> <p>12 sent out revised questionnaires or the old</p> <p>13 questionnaires?</p> <p>14 A. No, you would have to ask</p> <p>15 somebody in that group.</p> <p>16 Q. Okay. Now, do you see at the</p> <p>17 top of page 3 it says, "Work continues with</p> <p>18 IS on algorithms."</p> <p>19 A. Uh-huh.</p> <p>20 Q. "E-mail follows from Cathy</p> <p>21 Stewart."</p> <p>22 A. Right.</p> <p>23 Q. And can you review that e-mail</p> <p>24 for me?</p> <p>25 MR. TSAI: Dean, after we go</p>	<p style="text-align: right;">Page 205</p> <p>1 again, but my notes -- aren't very clear.</p> <p>2 This is a correct ship to report classes on</p> <p>3 this report is for total quantity."</p> <p>4 I think she was reviewing</p> <p>5 with -- what Robyn had presented to her and</p> <p>6 Cathy was just questioning if that's what she</p> <p>7 had asked for or not.</p> <p>8 Q. Okay. And then -- well, do you</p> <p>9 see the paragraph in the middle of the page</p> <p>10 that starts with, "This was -- this was we</p> <p>11 can see that this customer"?</p> <p>12 Do you see that?</p> <p>13 A. Uh-huh.</p> <p>14 Q. And then it's below the -- what</p> <p>15 appears to be both months and, I guess,</p> <p>16 hypothetical orders.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. So what -- what is</p> <p>20 Cathy's concern?</p> <p>21 A. I'm not sure. You would have</p> <p>22 to ask Cathy about that.</p> <p>23 Q. Okay.</p> <p>24 A. From -- this was -- okay. I</p> <p>25 think her -- what she was saying that</p>



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1 their -- their gradual increase of orders  
2 rather than jumping from 100 to 200 would  
3 trigger the 2 X formula versus if they  
4 gradually increase from 100 to 125 to 150 to  
5 175 would not trigger that -- that to kick  
6 out.

7 Q. In other words, it would be  
8 possible over time to actually have a  
9 significant increase in the monthly order  
10 that wouldn't be triggered by the algorithm;  
11 is that fair?

12 A. Right. And I think that's what  
13 Cathy is pointing out --

14 Q. Okay.

15 A. -- is that they could get  
16 around it that way. So we were trying to  
17 work on a system that everything that we  
18 possibly could think of of getting around  
19 placing an order that we didn't feel it was  
20 legitimate, we were trying to think of  
21 everything possible.

22 Q. And so how was this concern  
23 addressed?

24 A. I don't remember. I think it  
25 was addressed, but I don't remember exactly

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1 how.

2 Q. Okay. And so it was possible  
3 that it -- was it possible that it wasn't  
4 addressed?

5 A. I think you would have to talk  
6 to Cathy about that.

7 Q. Okay. Do you know --

8 A. Like I said, she was working on  
9 the dosage log rhythms {sic} and I was  
10 working on the bulk because that's what we  
11 were familiar with.

12 Q. Do you know if anyone else  
13 raised a similar concern, namely that you  
14 could have gradual increases that over time  
15 result in a significant increase that  
16 wouldn't be caught?

17 A. If anybody else --

18 Q. Yeah, do you know if this  
19 concern was raised by anyone else?

20 A. I'm not sure. It could have  
21 been. I mean, the team working on this was  
22 looking at all possibilities. They're trying  
23 to think of what they could do, somebody -- a  
24 customer could do to try and get around the  
25 system.

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1 Q. But -- but you're not aware  
2 of -- you're not aware of what fix, if any,  
3 was applied to address this concern?

4 A. No.

5 MR. KAWAMOTO: Okay. So why  
6 don't we take a break now.

7 VIDEOGRAPHER: We're going off  
8 the record at 2:35 p.m.

9 (Off the record at 2:35 p.m.)

10 VIDEOGRAPHER: We are back on  
11 the record at 2:51 p.m.

12 QUESTIONS BY MR. KAWAMOTO:

13 Q. So if we could return to the  
14 document that you were just looking at, I  
15 believe it is Exhibit 7.

16 A. Okay.

17 Q. Okay?

18 Now, you had -- we were  
19 discussing the gradual increase in orders  
20 over time, and you had indicated that's  
21 something that Cathy Stewart would be  
22 knowledgeable about in the dosage area.

23 A. That's correct.

24 Q. With respect to the bulk area,  
25 which was your area of expertise, wouldn't

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1 that same problem also apply?

2 A. Yeah, the same problem could  
3 apply, yes.

4 Q. And so how was that addressed  
5 in the bulk context?

6 A. I don't remember, but I'm  
7 sure -- is it in here? We would have put  
8 something in based upon the bulk side also.  
9 I don't remember exactly what it was.

10 Q. Well, how -- how would one fix  
11 this problem?

12 A. How would one fix this problem?

13 Q. Yes. I mean, hypothetically,  
14 how would you fix a problem? I mean, if you  
15 have a numeric formula that's based on  
16 looking at a current order and then comparing  
17 it to sort of prior order history, I mean,  
18 how would you -- how would you modify the  
19 formula to address that problem?

20 A. It would probably be based upon  
21 an average versus looking at -- and I'm just  
22 guessing at this point because I don't  
23 remember anymore. I'll just leave it at  
24 that: I don't remember anymore how we  
25 addressed it.

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1 Q. But mathematically speaking,  
2 what -- I mean, what would you do? Because,  
3 I mean, you're already basing that formula on  
4 an average, aren't you?

5 A. Correct. Average period of  
6 time of ordering.

7 Q. Yes.

8 A. Yes.

9 So if they went from 100 to 150  
10 to 175 to 200 over a period of time, I guess  
11 you would try to divide that and come up with  
12 an average. And if it went two times over  
13 that average, it might kick it out that way.

14 Q. Well, I mean, isn't the only  
15 way to decrease the [REDACTED] times -- so instead  
16 of looking at two times, you would look at,  
17 for example, [REDACTED]?

18 A. That's one approach. I'm not  
19 sure if that's the only approach.

20 Q. Well, what -- what -- what is  
21 the other approach that you're --

22 A. I think -- that's what I was  
23 just talking about. If you looked at the  
24 average of, say, 125, 150, 175, 200, which is  
25 a general increase, if you took that average

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1 Do you see that?

2 A. Uh-huh.

3 Q. So how long was the peculiar  
4 order report that you ultimately ended up  
5 reviewing after the program went live in fall  
6 of 2009?

7 A. It varied from day to day. On  
8 an average, I would say it's less than  
9 probably -- probably 10 or 15.

10 Q. And that's 10 or 15 pages?

11 A. Yes.

12 Q. And how many orders would be on  
13 that report?

14 A. Maybe five or so orders on a  
15 page.

16 Q. So anywhere from 25 to 50  
17 orders; is that fair?

18 A. It could be on a day, daily  
19 basis.

20 Q. And who was responsible for  
21 investigating and determining whether there  
22 was a valid business -- well, strike that.

23 What did you do with those 25  
24 or 50 orders that would show up on your  
25 report on a daily basis?

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1 and say it was 150, if the orders were two  
2 times that 150, then it would kick it out.  
3 That's one way of doing it.

4 Or you could do it like you  
5 said and make it [REDACTED] or [REDACTED] or [REDACTED] or --  
6 there's probably a number of ways of doing it  
7 besides that, but I don't remember what we  
8 landed on.

9 Q. And in terms of the average,  
10 though, you would -- so you would -- you  
11 would try to shorten the average period --  
12 I'm just trying to understand how modifying  
13 the average --

14 A. I understand what you're --  
15 what you're asking, but I don't remember what  
16 we did.

17 Q. Okay. And to be clear, you're  
18 not even sure that this problem was  
19 addressed, are you?

20 A. I don't remember.

21 Q. So turning to page 4, at the  
22 very top it says, "Work continues with IS  
23 peculiar order report being generated based  
24 upon algorithm settings that's 49 pages  
25 long."

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1 A. I would review them to see if  
2 there's anything that I saw that would kick  
3 that order out, because it would give us  
4 different histories of that particular  
5 customer and what they ordered and that type  
6 of thing. And if I could see something that  
7 would validate the order that was flagged, I  
8 would let the order go.

9 If I couldn't validate it, then  
10 I would go to the CSRs like I explained  
11 earlier, the process, CSR, business manager,  
12 sales rep, and try to get this explained.

13 Q. And were you doing all 25 to 50  
14 orders, or was someone else also doing orders  
15 for you?

16 A. I was doing it.

17 Q. So you were the only one  
18 essentially doing it?

19 A. Reviewing that.

20 And it could -- it could have  
21 been less. I don't remember particularly.  
22 It could have been five. I don't know, five  
23 to ten, if that many.

24 Q. And roughly how long did it  
25 take you? What's your -- well, strike that.

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1 What's your recollection as to  
2 how long it took you?  
3 A. A couple hours a day.  
4 And that didn't entail -- if  
5 I couldn't -- if I couldn't come up with a  
6 solution of bringing it to the business  
7 manager or to the sales rep, we tried to get  
8 it resolved as soon as possible, hopefully by  
9 the -- the end of the day, if possible. If  
10 not, it may take a day or two to be resolved,  
11 depending on where the sales person was or  
12 where the business manager -- if I couldn't  
13 get ahold of them right away. But those were  
14 not that many orders.  
15 Q. And so what's the maximum that  
16 you could review, the maximum number of  
17 orders that you could review at any day?  
18 A. The maximum that I could  
19 review?  
20 Q. Well, I mean, would it be  
21 possible for you to review 200 orders?  
22 MR. TSAI: Object to the form.  
23 THE WITNESS: No, but to answer  
24 your -- to answer that, I would say  
25 there was not the case where I was

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1 being asked to -- or seeing 200 orders  
2 on a daily basis.  
3 QUESTIONS BY MR. KAWAMOTO:  
4 Q. Was there anyone else at the  
5 company other than you that could review  
6 these orders?  
7 A. Yes. As I mentioned before,  
8 the customer service rep that sat in for me  
9 when I was not there.  
10 Q. But as a general matter, it was  
11 just you reviewing these orders?  
12 A. Correct.  
13 Q. And did you have other job  
14 responsibilities in addition to reviewing  
15 these orders?  
16 A. Yes.  
17 Q. What were they?  
18 A. I oversaw the customer service  
19 group. I had a pretty -- pretty senior  
20 group, so just solving problems or questions  
21 that they may have, meeting with other people  
22 on other business on a daily basis. But this  
23 was -- this was primary in the morning and  
24 the afternoon.  
25 Q. Well, it was -- if it was

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1 primary in the morning and the afternoon --  
2 A. Right. That's when the reports  
3 came out.  
4 Q. Okay. And so did they come out  
5 twice daily?  
6 A. I believe they did, yes.  
7 Q. And if this was primary for the  
8 morning and this was primary for the  
9 afternoon --  
10 A. It took up a good bit of my  
11 time.  
12 Q. Yes.  
13 When did you have time to get  
14 your other work done?  
15 MR. TSAI: Object to the form.  
16 THE WITNESS: Could you be more  
17 specific?  
18 QUESTIONS BY MR. KAWAMOTO:  
19 Q. Sure.  
20 If this was your primary task  
21 in the morning and your primary task in the  
22 afternoon -- I mean, the working day is  
23 generally just divided into morning and  
24 afternoon --  
25 A. Right.

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1 Q. -- so --  
2 A. Yeah, we're talking an hour or  
3 so in the morning and an hour or so in the  
4 afternoon of reviewing these orders.  
5 Q. And so do you see the entry,  
6 that 10/27/09, "peculiar order report being  
7 generated based on algorithm is 150 dosage  
8 orders per day and 170 bulk API orders per  
9 day"?  
10 A. I see that.  
11 Q. Okay. Would it have been  
12 possible for you to review 150 dosage orders  
13 per day?  
14 A. No, it would not.  
15 Now, keep in mind this was  
16 based upon the working document, or what we  
17 were looking at as far as suspicious order  
18 monitoring program based upon different  
19 criteria.  
20 Now, as we went along, there  
21 was some things that were not working that  
22 created this problem of having so many. That  
23 had nothing to do with what we wanted to look  
24 at, but it was put into the system.  
25 And I think you can say there

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1 was some statistical problems that needed to  
2 be fine-tuned. So it was kicking out orders  
3 that shouldn't have been kicked out.

4 And this was an IS -- this was  
5 an IS issue.

6 Q. And what is your basis for  
7 saying that it was kicking out orders that  
8 shouldn't have been kicked out?

9 Well, let me rephrase that.  
10 What are examples of orders that were being  
11 kicked out that shouldn't have been?

12 A. Well, right here, I don't  
13 remember exactly what this was about, where  
14 it says, "The 30-day cumulative algorithm is  
15 turned off because that specific trigger was  
16 not spelled out in HDMA guidance and has  
17 inflated the peculiar order count."

18 So that's one instance where it  
19 was inflating the number of orders that we  
20 were looking at.

21 Q. And what is the 30-day  
22 cumulative algorithm? Do you know what that  
23 is?

24 A. I don't remember.

25 Q. Now, from this entry, it

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1 indicates that the 30-day cumulative  
2 algorithm was not spelled out in HDMA  
3 guidance. But that's not the same thing as  
4 saying that this algorithm wasn't going to  
5 provide valuable information on peculiar  
6 orders, is it?

7 MR. TSAI: Object to the form.

8 THE WITNESS: No, I don't think  
9 it's saying that. I'm not sure what  
10 it's saying there.

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. Okay. Was there any analysis  
13 done on the impact of removing the 30-day  
14 cumulative algorithm with respect to the  
15 orders that were no longer being kicked out?

16 A. Well, as I had mentioned  
17 earlier, you know, what we did was we -- we  
18 test ran this and massaged it as it went  
19 along to see if it was doing the job we  
20 wanted it to do as far as looking at the  
21 orders based upon what we felt was needed,  
22 and it was adjusted as we went along. So  
23 that's all I can -- all I can remember.

24 Q. So with respect to this 30-day  
25 cumulative algorithm --

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1 A. Uh-huh.

2 Q. -- when you have it -- when you  
3 have it turned on, it is kicking out, you  
4 know, some amount of orders. Or I guess to  
5 put it more accurately, it's flagging a  
6 certain amount of orders as peculiar; is that  
7 correct?

8 A. Correct.

9 Q. And then when you remove this,  
10 when you turn it off, those orders are no  
11 longer flagged as peculiar; is that right?

12 A. Correct.

13 Q. Was any analysis ever done to,  
14 you know, verify or confirm that those orders  
15 were in fact not peculiar?

16 A. I don't remember.

17 Q. If that analysis were done, who  
18 would have it?

19 A. I'm not sure who would have it  
20 at this time.

21 Q. Now, as a practical matter, you  
22 can't review 150 orders per day, correct?

23 A. That would be difficult.

24 Q. And so if you had a program  
25 that were -- that was identifying 150 orders,

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1 just as a matter of resources, you would have  
2 to tweak that; isn't that correct?

3 A. And I think that's what this is  
4 showing here, is we were tweaking things that  
5 we felt that we could tweak without losing  
6 focus of what we intended to do.

7 And again, we weren't given any  
8 guidance on what it should be doing, but we  
9 felt we still had a pretty robust system, and  
10 just 150 orders were not within our -- our --  
11 able to do that at that time. So we felt by  
12 changing this we could still maintain a  
13 robust system.

14 Q. But part of what you were  
15 looking at in terms of designing this system  
16 was its ability to function given the  
17 resources that were assigned to it; is that  
18 fair?

19 A. I'm not sure if that's fair.  
20 We felt we -- we still felt with our end  
21 product that we had a good product, and with  
22 the resources that we had that we could  
23 manage it.

24 Q. Well, with respect to, for  
25 example, this 30-day cumulative algorithm, no



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1 one ever went back and actually reviewed the  
2 orders that were no longer being kicked out  
3 because the algorithm was turned off?

4 A. I didn't say that. I said I  
5 don't remember if somebody did or not.

6 Q. Do you feel that analysis  
7 should have been done before turning it off?

8 A. It probably should have and  
9 probably was; I just don't remember.

10 Q. And you don't know who would  
11 have done that analysis or how it would have  
12 been memorialized?

13 A. No, I don't.

14 Q. Then do you see down it says --  
15 the entry is 4/30/2010?

16 A. Yes.

17 Q. It says, "Peculiar order  
18 calculation change from [REDACTED] times factor to  
19 [REDACTED] times factor."

20 A. Okay.

21 Q. Is that consistent with your  
22 recollection of how the algorithm was  
23 modified?

24 A. Yes.

25 Q. Okay. What was the basis for

Page 223

1 changing it from [REDACTED] times to [REDACTED] times?

2 A. This -- the system had been  
3 implemented already. I believe it was the  
4 fall of 2009, right?

5 Q. I believe that's what you said.

6 A. Yeah.

7 So after months of working with  
8 it and not finding any peculiar orders became  
9 suspicious orders, we felt pretty -- pretty  
10 good about changing the number from [REDACTED] to [REDACTED]  
11 [REDACTED] So that's what we did.

12 And we ran that -- I ran that  
13 by Karen Harper, and Karen Harper agreed to  
14 that based upon us not having any suspicious  
15 orders, and we put that in place.

16 Q. And -- well, why [REDACTED] times  
17 instead of [REDACTED] times or [REDACTED] times?

18 A. That's the number that we came  
19 up with.

20 Q. And so sort of going back to a  
21 previous question that I've asked.

22 A. Uh-huh.

23 Q. With respect to the change from  
24 [REDACTED] times to [REDACTED] times, you know,  
25 presumably there are now orders that are --

Page 224

1 that would have been kicked out under the [REDACTED]  
2 times that were not kicked out under [REDACTED]  
3 times; is that correct?

4 A. That's true.

5 Q. Was there ever a trial run or  
6 an analysis done to confirm that those orders  
7 were not in fact peculiar?

8 A. On the ones that didn't kick  
9 out?

10 Q. Yes, on the ones that were no  
11 longer kicked out because of this  
12 programmatic change.

13 A. I don't remember. I don't know  
14 if we did or not.

15 Q. Okay. But you believe that is  
16 an analysis that should have been done; is  
17 that correct?

18 A. We probably did it, yes, but I  
19 don't remember exactly who did it or when it  
20 was done.

21 Q. Now, one of the things about  
22 increasing the factor from [REDACTED] times to [REDACTED]  
23 times is that it does -- it does -- well,  
24 strike that.

25 Do you recall Ms. Stewart's

Page 225

1 concern about a gradual -- gradual increases  
2 that was referenced on page 3 of this  
3 document?

4 A. Yes, I remember. Yes.

5 Q. Okay. So when you go from a  
6 [REDACTED] times to a [REDACTED] times factor, that is  
7 going to increase that concern or that risk,  
8 isn't it?

9 A. I -- yes.

10 Q. Okay. And so in this regard,  
11 with respect to this risk, meaning a gradual  
12 increase over time, this calculation is now  
13 less protective than it would have been if it  
14 were two times?

15 A. That's -- that's true. But  
16 keep in mind, we were not -- we were not  
17 the -- selling to the end user in that. Not  
18 only were we -- we weren't -- we were selling  
19 this material to the distributors and -- who  
20 had their own programs in place, and they  
21 were also responsible for reviewing the  
22 orders and customers that they were selling  
23 to.

24 So we felt even with the [REDACTED]  
25 where we weren't finding any issues with

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1 orders that we couldn't explain, and we -- we  
2 changed our process to the [REDACTED] and continued  
3 to monitor. And we changed it to [REDACTED], and we  
4 still didn't have any peculiar orders that  
5 became suspicious orders.

6 Q. Well, by --

7 A. But we felt comfortable in  
8 doing this at the time.

9 Q. By changing the formula from  
10 [REDACTED] to [REDACTED]

11 A. Right. And we discussed that,  
12 yes.

13 Q. Yes.

14 And it would -- it would -- I  
15 mean, well, one of the effects is that it  
16 decreased the number of orders you were  
17 reviewing, yes?

18 A. That's true.

19 Q. Do you recall how much of a  
20 decrease this was?

21 A. I don't -- I don't remember.

22 Q. Now, you indicated in your  
23 prior answer that -- well, strike that.

24 Is it fair to say that part of  
25 the reason Mallinckrodt was comfortable

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1 attention to page 7 of this memo, you see at  
2 the very bottom of the page it says, "Action  
3 plan"?

4 A. Okay.

5 Q. And in the middle of that  
6 paragraph at the very bottom it says, "The  
7 team believes the suspicious order monitoring  
8 program can be further enhanced by analyzing  
9 chargeback data for indirect customers and  
10 direct sales information available within  
11 existing systems."

12 Do you see that?

13 A. I do.

14 Q. Do you know if the suspicious  
15 order monitoring program was ever modified to  
16 take -- to analyze chargeback data?

17 A. Yes, it was. As part of our  
18 ongoing enhancement program for the  
19 suspicious order program, it was identified  
20 that the chargeback system could help us in  
21 identifying who the distributors were selling  
22 to. So eventually in 2010, this was -- the  
23 monitoring of suspicious orders were moved  
24 over to the chargeback team.

25 Q. And do you recall when in 2010

Page 227

1 making this change from [REDACTED] to [REDACTED] is  
2 because, as you indicated, the distributors  
3 have their own programs for suspicious  
4 orders?

5 A. Well, that was part of it.

6 Part of it was that we had not found any  
7 peculiar orders that became suspicious  
8 orders. And as we changed it to [REDACTED] and we  
9 had approval to do that, or I had approval to  
10 do that, we continued to monitor orders,  
11 peculiar orders, and again, we did not have  
12 any suspicious orders.

13 Q. What did you do to -- well,  
14 what did Mallinckrodt do to satisfy --  
15 satisfy itself that the distributors were  
16 implementing adequate SOM programs?

17 A. I wasn't -- I was just there at  
18 the beginning of this, but -- I should say,  
19 actually it probably started in 2009, but  
20 there was a team that was put together of  
21 Karen Harper and one of the legal people  
22 along with -- who would do audits with the  
23 distributors to see what programs they had in  
24 place.

25 Q. Now, if I could direct your

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1 this occurred?

2 A. Fall of 2010.

3 Q. And so were you still involved  
4 in the suspicious order monitoring program at  
5 that point?

6 A. The daily review was turned  
7 over to that department.

8 Q. So what you had previously  
9 described about how you would get 50 orders  
10 and then you would contact the --

11 A. Right.

12 Q. -- sales reps, that was no  
13 longer your responsibility?

14 A. Correct. It was turned over to  
15 this other group that had the chargeback  
16 information.

17 Q. Okay. And do you know who in  
18 this other group it was turned over to?

19 A. Tiffany is who I had mentioned  
20 earlier. I don't remember her last name.

21 Q. Okay. And do you know what  
22 procedure or process she followed?

23 A. No, I don't.

24 Q. Do you know if she continued to  
25 review these reports on a daily basis?

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1 A. I believe she did, yes.  
 2 Q. And she continued to  
 3 communicate with the sales reps?  
 4 A. I would imagine that would be  
 5 part of her process. I'm not sure what she  
 6 did once she took over it, but I explained to  
 7 her what I did and -- as far as what my  
 8 review -- what review I took as far as  
 9 talking to the sales reps and the business  
 10 managers. And they also had the chargeback  
 11 system in that group, so I'm sure it was used  
 12 to enhance the system.  
 13 Q. And you indicated that --  
 14 A. And I turned over all my files  
 15 over to her -- for her, to her group.  
 16 Q. And do you know how she used  
 17 the chargeback data?  
 18 A. I don't.  
 19 Q. Now, prior to 2010, did you  
 20 have access to the chargeback data?  
 21 A. I did not, no.  
 22 I think it was identified as a  
 23 source that we could implement to enhance our  
 24 system as we were looking for opportunities  
 25 for more information and that. That was

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1 pointed out as, hey, maybe we can use the  
 2 chargeback system.  
 3 Q. Well, how old is the chargeback  
 4 system?  
 5 A. It's been around for a long  
 6 time.  
 7 Q. So in 2008 and 2009, you had  
 8 chargeback data; is that correct?  
 9 A. We did.  
 10 Q. And so in -- so in theory, one  
 11 could have used this chargeback data, you  
 12 know, in 2007 or 2008 or 2009?  
 13 A. In theory it could have.  
 14 Q. So it's not as if Mallinckrodt  
 15 was collecting now data starting in 2010; it  
 16 was that it was using the data it had?  
 17 A. Yes, and we -- I don't remember  
 18 exactly how we -- you know, we finally  
 19 figured out, hey, maybe we can start, you  
 20 know, digging deeper into the -- into who our  
 21 customers were selling to also as part of an  
 22 enhancement.  
 23 (Mallinckrodt-Rausch Exhibit 8  
 24 marked for identification.)  
 25

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1 QUESTIONS BY MR. KAWAMOTO:  
 2 Q. So I'm marking another exhibit.  
 3 It is Exhibit 8.  
 4 A. Are we done with this one?  
 5 Q. Yes, we're done with that one.  
 6 And this has Bates number  
 7 MNK-T1\_264431.  
 8 A. Okay.  
 9 Q. Okay. Now, just as a matter of  
 10 chronology, the enhanced -- the enhanced SOM  
 11 program came online in 2000 -- in the fall  
 12 of 2009?  
 13 A. Yes.  
 14 Q. And in fall of 2010, your SOM  
 15 responsibilities were transferred to Tiffany?  
 16 A. That's correct.  
 17 Q. So you oversaw the enhanced SOM  
 18 program for dosage products for one year?  
 19 A. Correct.  
 20 Q. Okay. This document, it's  
 21 Bates-numbered MNK-10-1\_264431 {sic}, and it  
 22 purports to describe the peculiar order  
 23 process.  
 24 A. Okay.  
 25 Q. Based on your review, does this

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1 accurately describe what Mallinckrodt's  
 2 peculiar order process was from fall of 2009  
 3 to fall of 2010?  
 4 A. As -- as a peculiar order, yes.  
 5 Q. Okay. And then you'll note  
 6 that someone --  
 7 A. This is what I was trying to  
 8 describe to you earlier but probably didn't  
 9 do a very good job of it, where it summarizes  
 10 the API of the product.  
 11 Q. Okay. And you'll see how  
 12 the -- in the peculiar order criteria, the [REDACTED]  
 13 has been crossed out and someone has  
 14 substituted [REDACTED] in there.  
 15 A. Okay.  
 16 Q. So this would suggest that this  
 17 document was -- would have been prepared  
 18 sometime in 2010, because that's when that  
 19 decision was made?  
 20 A. Sometime in that time frame,  
 21 yes.  
 22 Q. Okay. Now, it says, "New  
 23 customers for dosage. Dosage will manually  
 24 establish the threshold limit."  
 25 What -- what is the threshold

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1 limit?

2 A. I believe the threshold limit,  
3 if I remember right, was based upon the  
4 customer class of what the average order  
5 amount was for that -- a customer of that  
6 type.

7 Since we had no previous orders  
8 from this customer, we -- we just took the  
9 average of what we were selling to customers  
10 like -- like them so we had some kind of  
11 basis to go on.

12 Q. And when you say "customer  
13 class," what do you mean by that?

14 A. Like distributor.

15 Q. So distributor verse wholesaler  
16 verse chain pharmacy, are those the different  
17 classes?

18 A. I would say so, yes.

19 Q. And the threshold limit is  
20 essentially -- it's the base that the  
21 algorithm would compare the current order to  
22 sort of the historic baseline; is that  
23 accurate?

24 A. Yes.

25 Q. So for the threshold -- well,

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1 strike that.

2 So one of the problems could be  
3 if your threshold limit were set too high,  
4 then, you know, orders that should be tagged  
5 as peculiar would not be; is that fair?

6 A. That's possible.

7 Q. All right. Now, you indicated  
8 that the threshold limit was set based on the  
9 average of all of the distributors.

10 A. I believe so. I think that's  
11 how it was done, yes.

12 Q. And for the distributors, was  
13 this -- was this average set on an  
14 industry-wide assessment of distributors, or  
15 was it just Mallinckrodt's distributor  
16 customers?

17 A. Mallinckrodt's.

18 Q. Okay. Now, distributors varied  
19 in size and geographic scope, didn't they?

20 A. I think we tried to take in  
21 effect how many -- how many different  
22 distributing warehouses they had, what their  
23 typical sales were, that type of thing, all  
24 the information that we could gather, and  
25 tried to make them comparable to customers

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1 that we already had on the books and get an  
2 average based upon that as our criteria to  
3 start with.

4 Q. Okay. So it sounds like you  
5 had distributor subclasses, essentially?

6 A. Yes.

7 (Mallinckrodt-Rausch Exhibit 9  
8 marked for identification.)

9 QUESTIONS BY MR. KAWAMOTO:

10 Q. Okay. So I'd like to mark as  
11 Exhibit 9 the following document, and this  
12 has a Bates number MNK-T1\_269399.

13 A. Okay.

14 Q. Okay. So this is a memo dated  
15 November 2, 2010, to Karen Harper from Howard  
16 Davis.

17 A. Okay.

18 Q. Do you know who Howard Davis  
19 is?

20 A. I believe he was with the DEA.

21 Q. Okay. And did you ever work  
22 with Howard Davis on anything while you were  
23 at Mallinckrodt?

24 A. No, I didn't. Not that I  
25 remember.

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1 Q. Okay. Do you know anything  
2 about Howard Davis other than he was with the  
3 DEA?

4 A. No.

5 Q. Okay. So in this memo he  
6 states -- well, let's start with the second  
7 full paragraph.

8 A. Okay.

9 Q. He states, "Federal register  
10 notices published as early as 2007 state  
11 specifically that using formulas that rely on  
12 percentages or averages over time has been  
13 determined by the DEA to be insufficient."

14 Do you agree with that  
15 statement?

16 A. Yes.

17 Q. Then skipping to the paragraph  
18 below that, it says, "An order must not be  
19 processed and filled if it's either  
20 suspicious or excessive. The existing SOP  
21 excels to meet this requirement through a  
22 specific evaluation process; however, the  
23 numeric formula is problematic. For example,  
24 should an occasion arise where an order is  
25 [REDACTED] over the historical average for



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1 that customer, an item, or in a situation  
 2 where the order meets but does not exceed the  
 3 three times criteria, it would theoretically  
 4 be filled through normal processing without  
 5 question -- without further question. In  
 6 doing so in certain cases and as noted in  
 7 recent immediate suspensions of other  
 8 large-scale DEA registrants, which are all a  
 9 matter of public record, Mallinckrodt would  
 10 be unnecessarily exposing itself to potential  
 11 liability."

12 Do you see that paragraph?

13 A. I do.

14 Q. Do you agree with that  
 15 statement?

16 MR. TSAI: Object to the form.

17 THE WITNESS: I understand -- I  
 18 hear -- I hear what he's saying, yes.

19 QUESTIONS BY MR. KAWAMOTO:

20 Q. Well, and do you agree with his  
 21 assessment?

22 A. Well, we -- we felt that we  
 23 were -- we had done with the [REDACTED] that we  
 24 didn't -- as I told you before, we felt  
 25 comfortable with going from [REDACTED] to [REDACTED] and I

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1 had Karen's approval. And apparently in due  
 2 diligence she talked to Howard Davis about  
 3 it, and in doing so, he was coming back  
 4 feeling that going from [REDACTED] to [REDACTED] would  
 5 be -- expose us to potential liability.

6 Q. Did you know that Karen Harper  
 7 talked to Howard Davis about the [REDACTED] to [REDACTED]  
 8 change?

9 A. I did not.

10 Q. Okay. If you had known that  
 11 Howard Davis had concerns about this [REDACTED]  
 12 change, would it have -- well, strike that.

13 Did you support the change from  
 14 [REDACTED] to [REDACTED]

15 A. Yes, at the time I did.

16 Q. If you had known that Howard  
 17 Davis had concerns about changing it from [REDACTED]  
 18 to [REDACTED] would that have mattered to your  
 19 support?

20 A. Of course it would have.

21 MR. TSAI: Object to the form.

22 THE WITNESS: Yes.

23 QUESTIONS BY MR. KAWAMOTO:

24 Q. Okay. And how would it have  
 25 mattered?

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1 A. We wouldn't -- we wouldn't have  
 2 changed it.

3 Q. Okay.

4 A. Keep in mind, we were -- you  
 5 know, we were on our own as far as developing  
 6 our programs. So, you know, Karen, on doing  
 7 her job as compliance manager, felt it was  
 8 important to keep the DEA in the progress of  
 9 our program that we had placed.

10 And I guess in seeing this --  
 11 and this is the first time I have seen it --  
 12 she apparently brought it to Howard's  
 13 attention that we had changed from [REDACTED] to  
 14 [REDACTED] and he apparently responded in this  
 15 manner.

16 Q. Okay. Now, turning to the  
 17 second page, it says, "Numeric formulas do  
 18 not identify circumstances that might be  
 19 indicative of diversion, such as ordering  
 20 larger quantities of a limited variety  
 21 regularly that would not otherwise be viewed  
 22 as suspicious, like ordering controlled  
 23 substances with few, if any, other drugs or  
 24 products, whether controlled or  
 25 noncontrolled, ordering highly abused

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1 controlled substances in limited quantities  
 2 disproportionate to other orders, or even  
 3 ordering the same controlled substances from  
 4 multiple suppliers."

5 Do you see that?

6 A. I see it.

7 Q. And do you agree that these are  
 8 all problems with numeric formulas?

9 A. These are all possibilities,  
 10 yes.

11 Q. Okay. And directing your  
 12 attention to Exhibit 2, so if you go back to  
 13 the start of the dep, which was that 2006 DEA  
 14 letter, these are the factors that the DEA  
 15 identified in that letter, aren't they?

16 A. Are you talking about the 10?

17 Q. I'm sorry, let me pull that  
 18 out.

19 Yes. If you look at Exhibit 2,  
 20 on page 3, Bates number 273565, it's the  
 21 circumstances that might be indicative of  
 22 diversion, and it lists out four different  
 23 things.

24 A. Oh. Yes, that's what he's  
 25 talking about there.

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1 Q. Okay. So these four things  
2 match up to the concerns that Howard is  
3 expressing?  
4 A. Yes.  
5 Q. And the DEA expressed these  
6 concerns in 2006, didn't they?  
7 A. It looks like it, yes.  
8 Q. Okay. Then underneath that  
9 there's another paragraph that says, "The DEA  
10 registrant population as a whole is now  
11 required to consider the totality of the  
12 circumstances when evaluating an order prior  
13 to it being filled."  
14 Do you under -- do you agree  
15 with that statement?  
16 A. Yes.  
17 Q. Okay. And underneath that,  
18 skipping further down, it says, "While not  
19 all-inclusive, recommended customer inquiries  
20 may include such factors as," and then this  
21 lists one, two, three, four, five, six, seven  
22 eight, nine -- nine different bullet points.  
23 Do you see those?  
24 A. I do.  
25 Q. And do you agree that all of

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1 these should be recommended customer  
2 inquiries?  
3 MR. TSAI: Object to the form.  
4 THE WITNESS: Let me look --  
5 read them.  
6 QUESTIONS BY MR. KAWAMOTO:  
7 Q. Sure.  
8 A. Okay.  
9 Q. Okay. So do you agree that  
10 this is all information that should be taken  
11 into account?  
12 A. I believe this was part of that  
13 checklist that was being sent out by the  
14 credit department, or CDIG, on a yearly basis  
15 for our customers to check whether they were  
16 doing that or not.  
17 Q. Okay. And so if Mallinckrodt's  
18 SOM program was not taking into account this  
19 information, you would view that as  
20 problematic, would you not?  
21 MR. TSAI: Object to the form.  
22 THE WITNESS: I would. But  
23 like I stated, I believe we were  
24 sending this out when new customers  
25 were being established. And on a

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1 yearly basis we were sending it out to  
2 our customers asking these questions,  
3 or similar questions, asking them if  
4 they'd fill it out and send it back to  
5 us for us to continue to sell to them.  
6 QUESTIONS BY MR. KAWAMOTO:  
7 Q. Do you know if any attempt was  
8 made to verify the information that the  
9 customers were providing in this regard?  
10 A. I don't know.  
11 Q. Okay. Should that information  
12 have been verified given its importance?  
13 A. I guess it would be.  
14 (Mallinckrodt-Rausch Exhibit 10  
15 marked for identification.)  
16 QUESTIONS BY MR. KAWAMOTO:  
17 Q. Now, this document also has an  
18 attachment which I'm going to mark as  
19 Exhibit 10, and the Bates number for this  
20 attachment is MNK-T1\_269401.  
21 Now, actually, I'm sorry, if I  
22 could interrupt you briefly.  
23 So going back to Exhibit 9,  
24 this memorandum.  
25 A. Okay.

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1 Q. Do you know what steps, if any,  
2 were taken to address Mr. Davis' concerns?  
3 A. This was written in  
4 November 2010, and I was no longer  
5 responsible for monitoring the orders. But  
6 like I mentioned earlier -- as far as the [REDACTED]  
7 and the [REDACTED] Okay?  
8 And like I stated earlier, I  
9 believe this was part of the checklist that  
10 we sent out to our -- our customers from  
11 CDIG.  
12 Q. But you don't know if anything  
13 was actually done to modify the enhanced SOM  
14 program to respond to Mr. Davis' concerns?  
15 A. I do not.  
16 Q. Okay. Okay. So can you -- can  
17 you review the MNK -- well, I'm sorry, can  
18 you review Exhibit 10?  
19 And I don't have detailed  
20 questions on all of it, but I do have some  
21 questions for you on this document.  
22 A. Is there a date on this or --  
23 Q. Well, this was an attachment to  
24 the Howard Davis memo, so it would presumably  
25 have the same date as the memo.

<p style="text-align: right;">Page 246</p> <p>1 A. Same date as the memo?</p> <p>2 Q. Yes.</p> <p>3 A. Okay.</p> <p>4 Q. So November of 2010.</p> <p>5 A. And who is this from?</p> <p>6 Q. Well, actually, if you look</p> <p>7 back at Exhibit 10 {sic}, the very bottom of</p> <p>8 the memo, Mr. Davis says, "I recommend the</p> <p>9 immediate revision of SOP number CS COMP 3.0</p> <p>10 to include additional definitive criteria as</p> <p>11 noted above." And then further down he says,</p> <p>12 "The new draft SOP entitled 'Due Diligence</p> <p>13 Procedures and Monitoring of Controlled</p> <p>14 Substances Sales' is included for</p> <p>15 consideration."</p> <p>16 A. Okay.</p> <p>17 Q. And that's what this document</p> <p>18 is.</p> <p>19 A. Oh, okay. So they were giving</p> <p>20 us information on standard operating</p> <p>21 procedure.</p> <p>22 Q. And if it helps your review, my</p> <p>23 questions relate to sections 4, 5, 7, 8 and 9</p> <p>24 of the memo.</p> <p>25 MR. TSAI: We've been going for</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. So Howard Davis is a -- I</p> <p>2 believe he is a former DEA personnel.</p> <p>3 A. Okay.</p> <p>4 Q. And he was working as a</p> <p>5 consultant for Mallinckrodt.</p> <p>6 A. Oh, okay.</p> <p>7 Q. I'm not -- I'm not positive</p> <p>8 exactly what his status was.</p> <p>9 A. Okay.</p> <p>10 Q. But apparently Ms. Harper asked</p> <p>11 him to review the S -- CS COMP 3.0 procedure,</p> <p>12 and he prepared her this memo --</p> <p>13 A. Okay.</p> <p>14 Q. -- with these recommendations.</p> <p>15 A. Oh, okay.</p> <p>16 Q. So I guess my -- one thing I</p> <p>17 wanted to ask you is that -- does that</p> <p>18 change -- does that change any of your prior</p> <p>19 testimony regarding Mr. Davis' views as he</p> <p>20 expressed in his memo?</p> <p>21 MR. TSAI: And I would like to</p> <p>22 object for the record that that line</p> <p>23 of questioning was -- didn't have that</p> <p>24 clarification. And if we're just</p> <p>25 clarifying the record, I think at this</p>
<p style="text-align: right;">Page 247</p> <p>1 about an hour. Is this a good time to</p> <p>2 take a break since this is a long</p> <p>3 document?</p> <p>4 MR. KAWAMOTO: Well -- okay.</p> <p>5 Well -- sure. Well, why don't I --</p> <p>6 THE WITNESS: I'm willing to</p> <p>7 go.</p> <p>8 MR. KAWAMOTO: Okay. Well,</p> <p>9 yeah -- well, why don't we keep going,</p> <p>10 and if for whatever reason you want to</p> <p>11 take a break, just let me know and I'm</p> <p>12 happy to take a break.</p> <p>13 THE WITNESS: Okay.</p> <p>14 QUESTIONS BY MR. KAWAMOTO:</p> <p>15 Q. So did you want to review some</p> <p>16 more, or should I just ask you questions?</p> <p>17 A. No, go ahead. I mean, I can</p> <p>18 look at it to --</p> <p>19 Q. Okay. So Section 4 is an</p> <p>20 affidavit requirement.</p> <p>21 A. Now, if I'm reading this right,</p> <p>22 this is from the DEA, I believe you said?</p> <p>23 Q. Well, no, that is something I</p> <p>24 wanted to clarify with you.</p> <p>25 A. Okay.</p>	<p style="text-align: right;">Page 249</p> <p>1 time when Exhibit 9 was written,</p> <p>2 Howard Davis was not speaking on</p> <p>3 behalf of the DEA or employed by the</p> <p>4 DEA.</p> <p>5 QUESTIONS BY MR. KAWAMOTO:</p> <p>6 Q. So with that -- with that</p> <p>7 clarification --</p> <p>8 A. Okay.</p> <p>9 Q. -- does that change your</p> <p>10 opinion of any of the views he's expressing</p> <p>11 in his memorandum?</p> <p>12 A. Does it change my opinion?</p> <p>13 What in particular did you want</p> <p>14 to talk about? 4 or the whole thing or --</p> <p>15 Q. Well, no, let's go back --</p> <p>16 let's go back. I didn't realize that --</p> <p>17 until I reviewed the transcript, I didn't</p> <p>18 realize there was that confusion.</p> <p>19 But going back to Exhibit 9 --</p> <p>20 A. So this was written by someone</p> <p>21 that I guess -- that we had -- that was a</p> <p>22 former DEA employee that we had consulted</p> <p>23 with to go over the -- our process --</p> <p>24 Q. Yes.</p> <p>25 A. -- and make recommendations?</p>

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1 Q. That is my understanding.  
 2 Well, you, I believe -- based on this memo,  
 3 it appears you asked him to review the  
 4 program.  
 5 A. When you say "you" --  
 6 Q. I believe Karen Harper.  
 7 A. -- Karen Harper did.  
 8 Q. Yes.  
 9 A. Okay. So I just want to  
 10 establish that this is something that Karen  
 11 Harper had asked him to review and reported  
 12 it back to him. This is the first time I've  
 13 seen this document, so --  
 14 MR. TSAI: And again, I'll  
 15 object for the record to that line of  
 16 questioning and testimony, given the  
 17 misunderstanding that was just put on  
 18 the record.  
 19 QUESTIONS BY MR. KAWAMOTO:  
 20 Q. Well, okay. In that case, why  
 21 don't we turn to Exhibit 9. So can you pick  
 22 up Exhibit 9 again?  
 23 A. Okay.  
 24 Q. So this -- this is -- this is  
 25 the memo that Mr. Davis prepared for

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1 Ms. Harper?  
 2 A. Oh, okay.  
 3 Q. Okay?  
 4 A. Okay. So that makes it a  
 5 little more clear that he wasn't working for  
 6 the DEA.  
 7 Q. He was not working for the DEA,  
 8 though he was formerly employed by them and  
 9 presumably had some expertise.  
 10 A. Right. And he had -- Karen had  
 11 asked him to review our process.  
 12 Q. Yes.  
 13 A. Okay.  
 14 Q. And so when he says, "Federal  
 15 register notices published as early as 2007  
 16 state specifically that using formulas that  
 17 rely on percentages or averages over time has  
 18 been determined by the DEA to be  
 19 insufficient," would you agree with that  
 20 statement?  
 21 MR. TSAI: Object to the form.  
 22 THE WITNESS: Where are you at?  
 23 I'm sorry.  
 24 QUESTIONS BY MR. KAWAMOTO:  
 25 Q. The middle of the second

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1 paragraph.  
 2 A. Okay. Yes, I would agree with  
 3 that.  
 4 Q. Okay. And the statement that  
 5 "an order must not be processed and filled if  
 6 it is either suspicious or excessive," you  
 7 would agree with that statement?  
 8 A. Okay.  
 9 Q. Well, I'm sorry, so --  
 10 A. I'm just seeing now, he's  
 11 reviewing -- this is a review and -- of -- by  
 12 Howard Davis. And he's -- he's telling Karen  
 13 that right now, as the -- the current process  
 14 is being done is that we have time frame --  
 15 or we decided that we could allow an order  
 16 determined as peculiar to go ahead and ship  
 17 as long as we continued to do our due process  
 18 of following up on the order to make sure it  
 19 was not becoming a suspicious order -- not a  
 20 suspicious order.  
 21 So I think that's what he's  
 22 addressing.  
 23 Q. Okay.  
 24 A. Addressing here.  
 25 Then he goes on to address the

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1 other portion of what was in place at the  
 2 time, that we changed it from [REDACTED] to [REDACTED]  
 3 Q. Uh-huh.  
 4 A. Okay? And he brought this up  
 5 as some concerns that he may have that we  
 6 might want to address.  
 7 Q. Okay. And so the statement he  
 8 has when "an order must not be processed and  
 9 filled if it is either suspicious or  
 10 excessive," do you agree with that statement?  
 11 Is he correct on that point?  
 12 A. I agree with what he is coming  
 13 back and telling us, that it should not be  
 14 shipped, okay?  
 15 And what I'm saying, as part of  
 16 our daily review prior to this, prior to  
 17 Howard Davis saying this, that we were going  
 18 ahead if the order was peculiar and we were  
 19 not able to completely vet the order -- and  
 20 what I mean by that is, as the sales  
 21 department or the salesmen or the marketing  
 22 person in a due fashion of time, that we  
 23 would go ahead and allow the order to ship,  
 24 and we would continue the process of  
 25 evaluating whether it should be moved to a



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1 suspicious order.

2 So he's coming back after  
3 review and saying, "This is something that  
4 you may want to not -- may not want to do."

5 Q. Okay. And do you agree with  
6 his assessment, that that is something that  
7 you don't want to do?

8 A. Well, at the time I don't -- I  
9 didn't agree with it. I felt that we -- we  
10 were doing our -- our job, and we had a  
11 six-month or five-month history of working at  
12 two months and not having an order that  
13 became -- went from peculiar to suspicious,  
14 and we felt it was okay based upon that to  
15 move it to three times. All right? So we  
16 felt that was okay. Karen approved.

17 And Howard came back, from what  
18 I'm reading here, and saying that you may  
19 want to change that. That's what I get out  
20 of it.

21 Q. Well, actually, what he's  
22 saying, if you just read the text, is, "An  
23 order must not be processed and filled if it  
24 is either suspicious or excessive."

25 So do you disagree with that

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1 statement?

2 Can an order be processed and  
3 filled if it is suspicious or excessive?

4 A. Well, it shouldn't if it's  
5 deemed suspicious.

6 Q. Okay. So if an order is -- if  
7 an order is either suspicious or excessive,  
8 it should not be processed and filled; is  
9 that fair?

10 A. That's what he's saying, yes, I  
11 agree with that.

12 Q. Then he goes on to say, "The  
13 existing SOP excels to meet this requirement  
14 through a specific evaluation process.  
15 However, the numeric formula is problematic.  
16 For example, should an occasion arise where  
17 an order is three times over the historical  
18 average for that customer and item, or in a  
19 situation where the order meets but does not  
20 exceed the three times criteria, it would  
21 theoretically be filled through normal  
22 processing without further question. In  
23 doing so, in certain cases and as noted in  
24 recent immediate suspensions of other  
25 large-scale DEA registrants, which are all a

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1 matter of public record, Mallinckrodt would  
2 be unnecessarily exposing itself to potential  
3 liability."

4 A. Okay.

5 Q. Do you see that statement?

6 A. I do.

7 Q. Do you agree with that, sir?

8 MR. TSAI: Object to the form.

9 THE WITNESS: I guess all I can  
10 say is that we felt that we could do  
11 that. And Howard, who was a former  
12 employee of the DEA, is saying as a  
13 consultant that you may want to relook  
14 at your -- and that's what Karen was  
15 doing, was asking him to review what  
16 we were doing and pointing out things  
17 that he felt that we might be liable  
18 for.

19 So in that case he's saying,  
20 you may want to review your [REDACTED] -- or  
21 your [REDACTED] program and change it to [REDACTED]  
22 because the potential for orders going  
23 through you might be liable for.

24 QUESTIONS BY MR. KAWAMOTO:

25 Q. And had How -- had you known

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1 that Howard had this concern, would you still  
2 have supported a change from the [REDACTED] to [REDACTED]

3 A. Well, I'm not sure when -- this  
4 was done in October, I believe.

5 Q. Oh, it's November of 2010.

6 A. November of 2010. And I  
7 believe we made that change prior to November  
8 of 2010. Okay?

9 And to answer your question,  
10 if -- if Howard pointed this out and Karen,  
11 you know, agreed with him, we would change it  
12 back to the [REDACTED]

13 Q. Well, putting Karen aside  
14 because --

15 A. Right.

16 Q. -- you don't know what Karen  
17 did, you know, after she received this memo,  
18 correct?

19 A. Right.

20 Q. So just from the standpoint of  
21 your support and your -- your support for the  
22 change from [REDACTED] to [REDACTED] --

23 A. Right.

24 Q. -- if Mr. Davis had sent this  
25 memo to you, would it have -- would it have

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1 affected your support for changing the  
 2 program from [REDACTED] to [REDACTED]  
 3 MR. TSAI: Object to the form.  
 4 THE WITNESS: It probably would  
 5 have.  
 6 QUESTIONS BY MR. KAWAMOTO:  
 7 Q. Okay.  
 8 A. I thought I had answered that,  
 9 but maybe I'll make it clear.  
 10 Q. And when you say "it probably  
 11 would have," would it have made it less  
 12 likely that you would have supported the [REDACTED]  
 13 to [REDACTED] change?  
 14 MR. TSAI: Object to the form.  
 15 THE WITNESS: If I had known a  
 16 person who was familiar with the DEA  
 17 and we had hired to evaluate our  
 18 program, and he thought that it was --  
 19 it was potentially liable to change it  
 20 from [REDACTED] to [REDACTED] I probably would not  
 21 have made that change.  
 22 QUESTIONS BY MR. KAWAMOTO:  
 23 Q. Okay. Now, flipping to the  
 24 next page that says, "Numeric formulas do not  
 25 identify circumstances that might be

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1 indicative of diversion."  
 2 Do you see that paragraph?  
 3 A. I'm sorry, say that again?  
 4 Which paragraph?  
 5 Q. Sure. It's the top paragraph  
 6 on page 2 of the memo.  
 7 A. Okay.  
 8 Q. It says, "Numeric formulas do  
 9 not identify circumstances."  
 10 Do you see that?  
 11 A. I do.  
 12 Q. Okay. And it identifies four  
 13 circumstances that are indicative of  
 14 diversion that wouldn't be captured by  
 15 numeric formula.  
 16 A. Okay.  
 17 Q. Do you agree with that  
 18 statement?  
 19 A. Well, what he's pointing out is  
 20 maybe things that we could add to our  
 21 program, and we were, of course, always ready  
 22 to take input from other resources.  
 23 I take it that's why we hired  
 24 Howard, to review our process and see if  
 25 there was anything that he felt that we could

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1 do to make it better.  
 2 Q. And what -- I mean,  
 3 specifically what he's doing here is he's  
 4 identifying various circumstances that aren't  
 5 captured by numeric formulas.  
 6 A. Okay.  
 7 Q. Would you agree that the four  
 8 circumstances he's identifying are not  
 9 captured by numeric formulas?  
 10 A. The four -- the four of them in  
 11 that paragraph?  
 12 Q. Yes, I believe so.  
 13 A. I'm not -- I'm not sure how we  
 14 would know or even ordering the same  
 15 controlled substance from multiple suppliers.  
 16 I'm not sure how we would know that.  
 17 Q. Okay. But you would agree,  
 18 though, that that is a factor that isn't  
 19 captured by a numeric formula --  
 20 A. That's true.  
 21 Q. -- putting aside the question?  
 22 Okay.  
 23 So with respect to these four  
 24 factors -- well, taking a step back.  
 25 You would agree that these four

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1 factors might be indicative of diversion; is  
 2 that fair?  
 3 MR. TSAI: Object to the form.  
 4 THE WITNESS: It's possible,  
 5 yes.  
 6 QUESTIONS BY MR. KAWAMOTO:  
 7 Q. Okay. And you would also agree  
 8 that these four factors are not captured by  
 9 numeric formula?  
 10 A. I think that's what he's  
 11 pointing out, yes.  
 12 Q. And you would agree with him on  
 13 that?  
 14 A. Yes.  
 15 Q. Okay. And then these four  
 16 factors were also the same ones indicated by  
 17 the DEA in September of 2006. This is  
 18 Exhibit 2.  
 19 A. Okay.  
 20 Q. Right. I just wanted to make  
 21 sure your testimony on that hasn't changed.  
 22 A. No, it hasn't changed.  
 23 Q. Okay. And then going to the  
 24 paragraph underneath the paragraph regarding  
 25 numeric formulas where it says, "The DEA



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1 registrant population as a whole is now  
 2 required to consider the totality of the  
 3 circumstances when evaluating an order prior  
 4 to it being filled."  
 5 Do you see that statement?  
 6 A. I do.  
 7 Q. And you would agree with that,  
 8 correct?  
 9 A. I agree.  
 10 Q. Okay. And then going down to  
 11 the nine bullet points that Mr. Davis  
 12 identifies as being important information to  
 13 gather from customers, you would still agree  
 14 that that is important information?  
 15 MR. TSAI: Object to the form.  
 16 THE WITNESS: I believe this --  
 17 yes, they would be important factors.  
 18 QUESTIONS BY MR. KAWAMOTO:  
 19 Q. Okay. So putting that document  
 20 aside and turning now to Exhibit 10. So --  
 21 A. I just was reading this last  
 22 one.  
 23 Q. Go ahead.  
 24 A. I wanted to see what he  
 25 recommended.

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1 Okay.  
 2 Q. Now, turning to --  
 3 A. This is the draft that he  
 4 prepared?  
 5 Q. Yes, this is the draft that he  
 6 prepared. This, I believe, is Exhibit 10.  
 7 A. Okay.  
 8 Q. So do you see on page -- or  
 9 Section 4 of this draft it says, "Affidavit"?  
 10 A. Okay.  
 11 Q. Okay.  
 12 A. Okay.  
 13 Q. Okay. So this -- this is --  
 14 Howard is proposing an affidavit requirement,  
 15 and the affidavit would verify that the  
 16 customer is not an online pharmacy and has  
 17 never conducted business as an Internet  
 18 pharmacy and is otherwise aware of their  
 19 corresponding responsibility for dispensing  
 20 controlled substances legitimately.  
 21 Do you see that?  
 22 A. I do.  
 23 Q. Do you think that this  
 24 requirement makes sense as part of a  
 25 suspicious order monitoring program?

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1 A. I do.  
 2 Q. Okay. Do you know if this  
 3 requirement was ever put in place?  
 4 A. I believe it was.  
 5 Q. Okay.  
 6 A. I believe it was part of the  
 7 CDIG checklist that was sent out to the  
 8 customers.  
 9 Q. Okay. Section 5, which is  
 10 background documentation. And these are  
 11 documents by customer type, asking the  
 12 customer specific questions about their  
 13 businesses and their licenses.  
 14 And can you review the various  
 15 questions?  
 16 A. Okay.  
 17 Q. Okay. Do you agree that it  
 18 makes sense to ask customers these types of  
 19 questions?  
 20 MR. TSAI: Object to the form.  
 21 QUESTIONS BY MR. KAWAMOTO:  
 22 Q. Well, let me rephrase that.  
 23 Do you agree that customers  
 24 should be asked the following questions that  
 25 he identifies?

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1 MR. TSAI: Object to the form.  
 2 THE WITNESS: I guess I agree  
 3 that these are things that should  
 4 be -- again, Howard, I guess, was  
 5 making recommendations, and I believe  
 6 that I shouldn't -- I shouldn't speak  
 7 out of turn because I was in customer  
 8 service. So this would have been part  
 9 of the CDIG process, so -- but I do  
 10 agree these are things that we could  
 11 possibly ask.  
 12 QUESTIONS BY MR. KAWAMOTO:  
 13 Q. Okay. And, well, not only  
 14 could you possibly ask for them, but you  
 15 would agree that it would be a good idea to  
 16 ask these questions?  
 17 MR. TSAI: Object to the form.  
 18 THE WITNESS: Like I said, it  
 19 would be a good idea.  
 20 QUESTIONS BY MR. KAWAMOTO:  
 21 Q. Okay. Then turning to  
 22 Section 7, it says "Memos."  
 23 A. Okay.  
 24 Q. Okay. Now, do you agree that  
 25 this would be a good modification to the

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1 suspicious order monitoring program?  
 2 A. I agree that it would enhance  
 3 it, yes.  
 4 Q. Okay. Do you know if this was  
 5 done?  
 6 A. I don't know.  
 7 Q. Okay. Then Section 8 is an  
 8 on-site inspection report. And it says, "If  
 9 a customer is flagged suspicious based on  
 10 their ordering habits or their due diligence  
 11 documents, then the compliance department may  
 12 require that an on-site inspection be  
 13 conducted by a third-party, experienced,  
 14 trained investigator."  
 15 Do you see that section?  
 16 A. Uh-huh, I do.  
 17 Q. Do you think that requirement  
 18 makes sense as an addition to the suspicious  
 19 order monitoring program?  
 20 A. You're asking me as a customer  
 21 service manager if I feel that this is --  
 22 would be important?  
 23 Q. Yes. And as someone that was  
 24 involved in setting up the SOM program, a  
 25 member of the SOM team.

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1 A. Well, this is -- this is  
 2 enhancements to the SMO {sic} team, and I  
 3 believe -- well, a form of this was done, as  
 4 I explained earlier, where Karen Harper and  
 5 the team were going ahead and making audits  
 6 on -- with customers. So that's as far as I  
 7 know what was implemented as of the time that  
 8 I was there.  
 9 Q. Do you know if Karen -- I  
 10 believe you previously testified that the  
 11 audits were conducted by Karen Harper and --  
 12 A. A team of other individuals.  
 13 I'm not sure who was all on the team. I know  
 14 one of our lawyers were, and there -- I'm not  
 15 sure if they went ahead and got an  
 16 investigator or not.  
 17 Q. Okay. So you don't know if  
 18 they used a third-party, experienced, trained  
 19 investigator?  
 20 A. I don't. I don't.  
 21 Q. Do you think it would have been  
 22 a good idea to do so?  
 23 A. It wouldn't have hurt.  
 24 Q. Okay. It also says, "The  
 25 investigator will visit the customer

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1 location, review documents, inspect the  
 2 customer's facility, observe the customer's  
 3 dispensing and/or examination practices,  
 4 request additional information from the  
 5 customer and complete an inspection report."  
 6 Do you agree that that would  
 7 have been factors that a third-party  
 8 investigator should have looked at?  
 9 MR. TSAI: Object to the form.  
 10 THE WITNESS: It's something  
 11 that could have been done, yes.  
 12 QUESTIONS BY MR. KAWAMOTO:  
 13 Q. Well, I mean -- well, strike  
 14 that.  
 15 Not only could it have been  
 16 done, but it would have enhanced the program,  
 17 would it not?  
 18 A. It would have enhanced any  
 19 program.  
 20 Q. Okay. Do you know if this was  
 21 actually done?  
 22 A. I don't know.  
 23 Q. Okay. Then Section 9 is  
 24 parameters used in defining orders of  
 25 interest.

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1 Do you see that?  
 2 A. I do.  
 3 Q. Okay. So orders of unusual  
 4 size would be a parameter that should be used  
 5 in defining an order of interest; is that  
 6 correct?  
 7 A. Yes.  
 8 Q. Okay. What about an order  
 9 deviating substantially from a normal  
 10 pattern?  
 11 A. Yes.  
 12 Q. What about orders of unusual  
 13 frequency?  
 14 A. Yes.  
 15 Q. What about will call orders,  
 16 meaning requested to be picked up?  
 17 A. We didn't -- we didn't allow  
 18 will call orders that I remember in the  
 19 dosage group.  
 20 Q. Okay. What about orders to be  
 21 delivered -- well, so strike that.  
 22 So will call orders then should  
 23 not have been permitted?  
 24 A. I want to say that it wasn't,  
 25 but I can't verify -- say for sure that that



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1 was true. I don't --  
 2 Q. I'm sorry, go ahead.  
 3 A. Go ahead.  
 4 Q. But in your opinion, will call  
 5 orders should not have been permitted?  
 6 A. I would -- I would say that  
 7 that's true.  
 8 Q. Okay. Orders to be delivered  
 9 to a different location, that should also not  
 10 have been permitted?  
 11 A. I agree.  
 12 Q. Okay. Cash orders should not  
 13 have been permitted?  
 14 A. I don't -- yes, I agree.  
 15 Q. And orders placed out of a  
 16 scope of the customer's field of practice,  
 17 that should not have been permitted?  
 18 MR. TSAI: Objection to the  
 19 form.  
 20 THE WITNESS: I'm not sure if I  
 21 understand what he's saying here, "out  
 22 of the scope of the customer's field  
 23 of practice." I'm not sure I know  
 24 what that is.  
 25

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1 QUESTIONS BY MR. KAWAMOTO:  
 2 Q. Okay. Could he be referencing,  
 3 for example, if you have a customer of a  
 4 distributor that is, you know, in a certain  
 5 practice area and they are prescribing drugs  
 6 that are generally not used by that practice  
 7 area?  
 8 MR. TSAI: Object to the form.  
 9 THE WITNESS: I'm not really  
 10 sure what he's -- what he's saying  
 11 here. I'm not sure if that's -- what  
 12 you're saying is right or not.  
 13 QUESTIONS BY MR. KAWAMOTO:  
 14 Q. Okay. And then the next bullet  
 15 point is, "Orders placed for more than one  
 16 controlled substance that are known to be  
 17 taken together, drug combinations, outside of  
 18 normal prescribing and patient treatment  
 19 practices. Such an example may be narcotics  
 20 with benzodiazapines, Soma and sleep aids  
 21 known as narcotic cocktails."  
 22 So do you believe that these  
 23 types of orders should not have -- that these  
 24 types of orders should not have been placed?  
 25 MR. TSAI: Object to the form.

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1 THE WITNESS: I would say that  
 2 that would be an enhancement, yes.  
 3 QUESTIONS BY MR. KAWAMOTO:  
 4 Q. Okay. And then actually if you  
 5 look -- do you see number 1 below Section 9?  
 6 A. I do.  
 7 Q. It says, "A physician or  
 8 veterinarian orders certain controlled  
 9 substances that are not consistent with a  
 10 type of practice identified by the  
 11 practitioner's licenses."  
 12 So that would, I imagine, be an  
 13 example of an order placed out of a scope of  
 14 a customer's field of practice?  
 15 A. Yes, I would agree with that.  
 16 Q. Okay. And so that is something  
 17 that should have been considered in  
 18 determining whether or not to fill an order;  
 19 is that correct?  
 20 MR. TSAI: Object to the form.  
 21 THE WITNESS: I -- I would  
 22 agree with that other -- other than we  
 23 weren't filling orders from physicians  
 24 or veterinarians. I'm not sure where  
 25 this is coming from.

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1 QUESTIONS BY MR. KAWAMOTO:  
 2 Q. Okay. So that's all I have on  
 3 that exhibit.  
 4 MR. KAWAMOTO: Rocky, did you  
 5 want to take a break now?  
 6 MR. TSAI: Let's take a break.  
 7 MR. KAWAMOTO: Okay.  
 8 VIDEOGRAPHER: We're going off  
 9 the record at 4:11 p.m.  
 10 (Off the record at 4:11 p.m.)  
 11 VIDEOGRAPHER: We are back on  
 12 the record at 4:31 p.m.  
 13 QUESTIONS BY MR. KAWAMOTO:  
 14 Q. Okay. So, Mr. Rausch, the last  
 15 topic I want to cover with you is the  
 16 clearing of suspicious orders. And what I  
 17 mean by that is you had previously indicated  
 18 that you would receive these reports, and  
 19 then you would contact various people  
 20 regarding the justification.  
 21 A. Right.  
 22 Q. And so just so, you know, both  
 23 of us are on the same page as to my  
 24 questions --  
 25 A. Yes.

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1 Q. -- I want to explore that  
2 process.

3 A. Okay.

4 Q. Now, would you agree with the  
5 statement that it's important to formally  
6 document the investigation of a peculiar  
7 order, including the hows and whys of the  
8 logic that was used to determine that the  
9 order was either appropriate or inappropriate  
10 to ship?

11 A. I can tell you what we did.

12 Q. Okay. What did you do then?

13 A. Okay. So we would get the  
14 reports, and as I had talked earlier, we had  
15 several orders on that report that were  
16 flagged as peculiar. And I would go down the  
17 line, as I had mentioned earlier, and look at  
18 why it was kicking out. There was different  
19 flags, reasons, that would be checked on why  
20 the order would be flagged. So I would take  
21 a look at that.

22 And then I would take a look at  
23 reports that I had to my disposal and see if  
24 there was anything else that I could see  
25 that may be why the order had been flagged

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1 that would be okay. Okay?

2 If I could not determine  
3 through what I had available to me, then I  
4 would go to the CSR, then to the business  
5 manager and then to the sales force. And I  
6 would send out e-mails to the folks, if I  
7 needed to, and document that and attach that  
8 to the report. Okay?

9 And then this was filed in the  
10 file folder for the month. I believe it's  
11 for the month.

12 Q. And the documentation of the  
13 order with respect to the information you  
14 received from either the CSR or the business  
15 manager or the sales force, that consisted of  
16 whatever they e-mailed in response to you?

17 A. Yes.

18 Q. So there was no formal,  
19 separate report or memo that was prepared?

20 A. No. No.

21 (Mallinckrodt-Rausch Exhibit 11  
22 marked for identification.)

23 QUESTIONS BY MR. KAWAMOTO:

24 Q. Okay. So I'd like to mark this  
25 as Exhibit 11, and it is -- let's see. It

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1 bears the Bates number MNK-T1\_307119.

2 And this is an e-mail exchange  
3 between you and, I believe, people in sales  
4 regarding a suspicious order and the business  
5 justification for it; is that fair?

6 A. Yes. Let me read it here.

7 Q. Okay.

8 A. Okay. This was a bulk  
9 customer.

10 Q. Okay. And do you recall  
11 sending or receiving these e-mails?

12 A. I do.

13 Q. Okay. So the top e-mail, it's  
14 to Bill Ratliff, who is director of security.

15 A. Right.

16 Q. And it says, "See the  
17 information below. Sovereign is an  
18 established customer that we have dealt with  
19 for years. They are a contract manufacturer  
20 that may have gotten some new business. Let  
21 me know if we need to do anything else."

22 So this e-mail is the -- is a  
23 complete report with respect to the  
24 justification for shipping this order; is  
25 that fair?

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1 A. I'm not sure if it's the  
2 complete report. I don't see a response from  
3 Bill.

4 Q. Okay.

5 A. So I'm sure there was, you  
6 know, continued e-mails on what he -- if he  
7 gave his approval or not.

8 Q. Okay. Now, it says they're a  
9 contract manufacturer that may have gotten  
10 some new business.

11 A. That's -- okay.

12 Q. Do you see the "may"?

13 A. Yes.

14 Q. So that indicates that you  
15 weren't sure whether they had gotten new  
16 business. You thought they may have?

17 A. That's what Tom Palmer is  
18 saying, yes.

19 Q. Okay. So do you know if Tom  
20 took any steps to verify that they in fact  
21 had new business?

22 A. I cannot tell that from what he  
23 put in this e-mail.

24 Q. Okay. Did you take any steps  
25 to verify that they in fact had gotten some

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1 new business?  
 2 A. You know, he mentions here that  
 3 both Marilyn and Camille are aware of the  
 4 situation. If he learns any more, he would  
 5 let us know.  
 6 So, you know, without all the  
 7 communication that was involved in this  
 8 e-mail, I can't really answer that question  
 9 because I don't see a response from Bill here  
 10 and any continued communication what  
 11 occurred. So to say if this is complete, I  
 12 would say, no, it is not complete.  
 13 Q. Okay. So do you recall taking  
 14 any additional steps to verify this  
 15 information?  
 16 A. I don't remember. I don't  
 17 remember, to answer your question.  
 18 Q. Okay. You indicate, you say,  
 19 "Bill, let me know if we need to do anything  
 20 else."  
 21 A. Right.  
 22 Q. So if Bill were to say no, then  
 23 I assume this would be the complete record;  
 24 is that correct?  
 25 A. "No" meaning that we should not

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1 ship it or we would --  
 2 Q. No. If Bill says, no, we don't  
 3 need to do anything else, if Bill approves  
 4 this for shipment, then this is a complete  
 5 record?  
 6 A. I believe so, yes.  
 7 Q. Okay. And you don't recall  
 8 whether Bill said yes or not?  
 9 A. I don't see a response here, so  
 10 I don't remember, no.  
 11 Q. Okay.  
 12 A. This was, you know, not --  
 13 Q. Was it Bill --  
 14 A. Ten years ago.  
 15 Q. Was it Bill's general practice  
 16 to request for more information, or did he  
 17 generally just approve these?  
 18 A. No, he -- he would -- he would  
 19 do -- he would look into it, yes.  
 20 (Mallinckrodt-Rausch Exhibit 12  
 21 marked for identification.)  
 22 QUESTIONS BY MR. KAWAMOTO:  
 23 Q. Okay. So this is another  
 24 exhibit. I'm marking it as Exhibit 12, and  
 25 it bears the Bates number 266788.

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1 A. Okay.  
 2 Q. Okay. Do you recall sending  
 3 and receiving this e-mail?  
 4 A. I don't recall, but I -- I'm  
 5 sure -- I'm sure I sent it.  
 6 Q. Okay. And this is an e-mail  
 7 from you to Kate and Kate to you --  
 8 A. Correct.  
 9 Q. -- regarding an oxycodone  
 10 order.  
 11 A. Yes.  
 12 Q. And, you know, you're flagging  
 13 an increase in the order.  
 14 A. Correct.  
 15 Q. And Kate's response is, "Jim,  
 16 we are the secondary with CVS Caremark and  
 17 this product. There is only one other  
 18 supplier in the market, so my guess is that  
 19 they're not able to get it from them and have  
 20 ordered from us."  
 21 A. Okay.  
 22 Q. "I don't think it is too big of  
 23 a reason to be alarmed. Thanks, Kate."  
 24 A. Okay. Kate was the business  
 25 person for the product.

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1 Q. Okay. And so she's saying it's  
 2 her guess --  
 3 A. Right.  
 4 Q. -- that that's why this is.  
 5 A. Right.  
 6 Q. Do you know if she did anything  
 7 to verify her guess?  
 8 A. I would have probably reached  
 9 out to the salesperson.  
 10 Q. Okay. And who is the  
 11 salesperson?  
 12 A. I don't remember who the  
 13 salesperson was for Caremark at this -- off  
 14 the top of my head, I don't remember who it  
 15 is.  
 16 Q. But you would have taken steps  
 17 to verify Kate's guess?  
 18 A. Yeah, my -- my guess is not  
 19 good enough for allowing this order to go  
 20 out, I don't believe.  
 21 Q. Okay. So this should have been  
 22 verified?  
 23 A. Yes.  
 24 Q. And presumably that  
 25 verification would have been attached to the

<p style="text-align: right;">Page 282</p> <p>1 suspicious order report?</p> <p>2 A. I would have hoped so, yes.</p> <p>3 Q. Okay. And it was your practice</p> <p>4 to attach any verification?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. If this wasn't verified</p> <p>7 and this went out just based on Kate's guess,</p> <p>8 that would -- in your view, that would be a</p> <p>9 problem?</p> <p>10 A. It could be a problem, yes.</p> <p>11 (Mallinckrodt-Rausch Exhibit 13</p> <p>12 marked for identification.)</p> <p>13 QUESTIONS BY MR. KAWAMOTO:</p> <p>14 Q. Okay. So this is now</p> <p>15 Exhibit 13, and it's being tagged as MN --</p> <p>16 I'm sorry, bears the Bates number</p> <p>17 MNK-T1_266996.</p> <p>18 A. Okay.</p> <p>19 Q. Okay. So this is another</p> <p>20 e-mail chain between you and Kate</p> <p>21 Muhlenkamp --</p> <p>22 A. All right.</p> <p>23 Q. -- regarding a suspicious</p> <p>24 order. Or I'm sorry, regarding a peculiar</p> <p>25 order. And --</p>	<p style="text-align: right;">Page 284</p> <p>1 it was verified, it would have been</p> <p>2 documented as an e-mail attached to the</p> <p>3 suspicious order report, correct?</p> <p>4 A. It could have been, yes.</p> <p>5 Q. Okay.</p> <p>6 A. Should have been.</p> <p>7 Q. Now, the suspicious order</p> <p>8 report, I believe, is that on Bates</p> <p>9 number 266995?</p> <p>10 A. Is it what? I'm sorry?</p> <p>11 Q. I'm looking at Bates</p> <p>12 number 266995. It's a list of orders.</p> <p>13 A. Okay.</p> <p>14 Q. Is that the suspicious order</p> <p>15 report?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And then behind that, on</p> <p>18 page 266997, that's the actual orders; is</p> <p>19 that correct?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. So, you know, the</p> <p>22 complete --</p> <p>23 A. Is there an order number here?</p> <p>24 Q. Sure.</p> <p>25 A. I'm just seeing if it had the</p>
<p style="text-align: right;">Page 283</p> <p>1 A. Okay.</p> <p>2 Q. -- what she says to you is,</p> <p>3 "Jim, I followed up with Steve Becker."</p> <p>4 Would Steve Becker have been</p> <p>5 the business person?</p> <p>6 A. He would have been the</p> <p>7 salesperson, I believe.</p> <p>8 Q. The salesperson? Okay.</p> <p>9 A. Uh-huh.</p> <p>10 Q. "He noted that Henry Schein had</p> <p>11 recently made changes to their internal</p> <p>12 structure and are now servicing additional</p> <p>13 third-party contracts, chargebacks, which may</p> <p>14 be driving their new demand. He was not</p> <p>15 surprised that they had started ordering.</p> <p>16 Hope this helps."</p> <p>17 Do you know if any steps were</p> <p>18 taken to verify that the internal structure</p> <p>19 was in fact driving the new demand?</p> <p>20 A. I don't remember.</p> <p>21 Q. Okay. Should additional steps</p> <p>22 have been taken to verify that?</p> <p>23 A. It could have been warranted,</p> <p>24 yes.</p> <p>25 Q. Okay. And if -- if, in fact,</p>	<p style="text-align: right;">Page 285</p> <p>1 order number on there.</p> <p>2 I'm seeing whether it</p> <p>3 referenced anything that is quoted in the</p> <p>4 e-mail. I'm trying to see if there's</p> <p>5 anything about 456 bottles on here. I don't</p> <p>6 see that.</p> <p>7 And this is dated -- this is</p> <p>8 dated April 26th, and this report's dated</p> <p>9 4/23.</p> <p>10 I'm trying to see if there's</p> <p>11 something that's -- identifies on this report</p> <p>12 this -- what we were e-mailing about. I see</p> <p>13 Henry Schein, but I don't see the order</p> <p>14 quantity that was talked about.</p> <p>15 It says 456, and I don't see</p> <p>16 that on -- on what's attached here.</p> <p>17 So anyway -- okay. So I'm</p> <p>18 assuming that what's attached here is</p> <p>19 referencing an order that the e-mail is</p> <p>20 talking to.</p> <p>21 Q. Okay. So this -- this e-mail</p> <p>22 then would have been the just -- the complete</p> <p>23 justification for shipping this order?</p> <p>24 A. I believe so.</p> <p>25 Q. Okay. And so no steps were</p>



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1 taken then to verify that in fact the  
2 internal structure was what was driving their  
3 demand; is that correct?

4 A. I imagine this was the end of  
5 it, yes.

6 Q. Okay. And so this -- okay.  
7 Strike that.

8 (Mallinckrodt-Rausch Exhibit 14  
9 marked for identification.)

10 QUESTIONS BY MR. KAWAMOTO:

11 Q. So I'd like to mark this as  
12 Exhibit 14, and it bears a Bates number  
13 MNK-T1\_266735.

14 A. Okay.

15 Q. Okay. Now, this is an e-mail  
16 exchange between you and Penny Myers.  
17 Who is Penny Myers?

18 A. She was a business manager.

19 Q. Okay. And this is -- do you  
20 recall receiving -- well, do you recall  
21 sending and receiving these e-mails?

22 A. I don't recall it, but I -- I  
23 wrote it, so, yes.

24 Q. Okay. And you were -- you were  
25 asking her about a suspicious order from

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1 say, okay, and from what I read here is she's  
2 saying, okay, based upon estimates from the  
3 customers of how much they'll be purchasing,  
4 we offered them a price. Okay?

5 If they don't purchase close to  
6 that amount, we -- the amount they estimate,  
7 we encourage them to do that or their price  
8 may be adjusted. Okay?

9 So based upon their volume,  
10 they -- they would -- you can buy at  
11 different tiers, is what I'm assuming this is  
12 saying.

13 Q. So in other words, if they  
14 don't purchase close to their estimated  
15 quantity, there's a financial, you know,  
16 penalty or consequence that gets attached; is  
17 that fair?

18 A. We're -- from what I read, it  
19 sounds that -- when you say "penalty," no,  
20 they're telling us that, okay, based upon the  
21 amount that they estimated to be buying from,  
22 we quote them a price. Okay? If they don't  
23 buy that, then we're probably going to have  
24 to increase the price.

25 Q. Okay.

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1 HD Smith -- or, I'm sorry, a peculiar order  
2 for HD Smith, and Penny indicates to you that  
3 the order is due to increased compliance and  
4 new pharmacies being added.

5 And then you ask her, "What is  
6 increased compliance?" and the answer she  
7 gives you is above.

8 Is this the complete record for  
9 the justification of this order?

10 A. I don't remember.

11 Q. Okay. Now, increased  
12 compliance. Now, Penny -- well, strike that.

13 You asked her what increased  
14 compliance is, and Penny responds, "When we  
15 offer a price, we asked for the estimated  
16 quantity that they will purchase. If they  
17 don't purchase close to the amount they  
18 estimated, we encourage them to do that or  
19 their price may not remain the same or their  
20 VIP provision may change."

21 Do you see that?

22 A. I do.

23 Q. And what do you understand her  
24 to be saying with that?

25 A. What I'm understanding her to

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1 A. You called it a penalty. We  
2 call it -- I wouldn't call it a penalty.

3 Q. But it would be fair to say  
4 they are getting a less favorable price?

5 A. Correct.

6 Q. So they have a financial  
7 incentive from Mallinckrodt to increase their  
8 order; is that fair?

9 A. Correct.

10 Q. Okay. So in essence, in the  
11 context of this e-mail, there is a financial  
12 incentive from Mallinckrodt to have this  
13 seller essentially put in a peculiar order?

14 MR. TSAI: Object to the form.

15 THE WITNESS: No, I wouldn't  
16 say a peculiar order.

17 QUESTIONS BY MR. KAWAMOTO:

18 Q. Well, this order was flagged in  
19 the system as a peculiar order, was it not?

20 A. It was. Okay. So what  
21 they're -- what it is is that, okay, the  
22 order is more than what they've ordered in  
23 the past. The system flagged it. The  
24 business manager reached out to the sales --  
25 to the customer -- or came back to Penny and

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1 said, "This is the reason why the orders have  
2 increased, because we've given them a better  
3 price if they buy more." So that was  
4 justification for the order.

5 Q. Okay. And you don't know if  
6 they actually had an increase in demand,  
7 right? Well, strike that.

8 A. I don't know that.

9 Q. There's no indication that they  
10 had an increase in demand. They might well  
11 be purchasing this additional amount because  
12 they don't want to have to pay the increased  
13 price?

14 A. I don't know. That's  
15 speculation. I can't answer that.

16 Q. But there's nothing in this  
17 e-mail that indicates that they are --

18 A. One way or the other.

19 Q. Yes.

20 Okay. So they are -- according  
21 to this e-mail, the reason they're asking for  
22 significant -- for significantly more than  
23 they previously asked for is because they  
24 don't want to have to pay a less favorable  
25 price; is that fair?

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1 A. That's correct.

2 But that was -- that was the  
3 reason why it hit the peculiar order report,  
4 and this was the responses back of why.

5 (Mallinckrodt-Rausch Exhibit 15  
6 marked for identification.)

7 QUESTIONS BY MR. KAWAMOTO:

8 Q. I'm going to mark this document  
9 as Exhibit 15, and this is MNK-T1\_266730.

10 Actually, I'm sorry, I just had  
11 one more question on Exhibit 14, the  
12 compliance e-mail.

13 Could you turn to that again?

14 A. I'm sorry, which one?

15 Q. The prior one.

16 A. This one.

17 Q. So I think it's Exhibit 14.

18 A. Exhibit 14? Okay.

19 Q. So the increased compliance  
20 justification, that would have been  
21 sufficient to justify shipping the order?

22 A. Yes.

23 Q. Okay. Thank you.

24 So now we're on Exhibit 15?

25 A. Yes.

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1 Okay.

2 Q. Okay. So this is an e-mail  
3 between you and Lisa Lundergan.

4 Who is Lisa Lundergan?

5 A. I believe she was a business  
6 manager.

7 Q. Okay. And do you recall  
8 sending or receiving these e-mails?

9 A. I don't recall it, but I see  
10 that I did.

11 Q. Okay. And then this -- this  
12 involves an order for 44,208 bottles of  
13 morphine oral --

14 A. Okay.

15 Q. -- which was three times more  
16 than they had ever placed before, and hence  
17 it tripped the algorithm.

18 A. Correct.

19 Q. And Lisa's response to your  
20 question as to why they are placing such an  
21 order is, "Yes, we are offering them the  
22 remainder of our inventory for morphine oral  
23 since it was being discontinued. Thank you  
24 for checking."

25 A. Okay.

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1 Q. Would that justification have  
2 been sufficient for you to ship this order?

3 A. Yes.

4 Q. Okay. Is it a cause for a  
5 concern that -- well, strike that.

6 (Mallinckrodt-Rausch Exhibit 16  
7 marked for identification.)

8 QUESTIONS BY MR. KAWAMOTO:

9 Q. Okay. So this is Exhibit 16  
10 now. It bears the Bates number  
11 MNK-T1\_298447.

12 A. Okay.

13 Q. So this says, "Cardinal placed  
14 a large order for" -- 851501, I believe  
15 that's the order number -- "for  
16 12,720 bottles" -- I'm sorry, let me take a  
17 step back.

18 So this is an e-mail between  
19 you and Kate Muhlenkamp again?

20 A. Correct.

21 Q. Do you recall receiving or  
22 sending these e-mails?

23 A. No.

24 Q. Okay. Do you have any reason  
25 to doubt that you did send or receive them?

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1 A. No.

2 Q. Okay. And so the e-mail -- the  
3 e-mail from you to Kate is that Cardinal has  
4 placed an order for 12,720 bottles, and their  
5 average has been 3,227.

6 A. Okay.

7 Q. And you wanted to know why  
8 they're increasing their inventory for these  
9 two products.

10 A. Okay.

11 Q. And her response is that she  
12 has been working with Cardinal to increase  
13 their inventories.

14 A. Correct.

15 Q. Okay. Would that have been a  
16 sufficient justification to ship this order?

17 A. Yes.

18 Q. Okay. Do you know why Kate was  
19 working with Cardinal to increase their  
20 inventories?

21 A. I don't remember, no.

22 Q. Okay. Was it -- was it a  
23 concern to Mallinckrodt if a distributor was  
24 accumulating an excessively large inventory of  
25 opioid products?

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1 MR. TSAI: Object to the form.

2 THE WITNESS: I think what Kate  
3 was doing here was that Cardinal --  
4 well, I shouldn't -- I shouldn't  
5 speculate. I don't know what -- how  
6 to answer that.

7 It would have been a concern,  
8 well, our business manager felt that  
9 it was appropriate that we reached out  
10 to them and asked them for reasons  
11 that I can't answer right now, to go  
12 ahead -- if they would go ahead and  
13 increase their inventories.

14 QUESTIONS BY MR. KAWAMOTO:

15 Q. From a diversion control  
16 standpoint, though, is it a concern when a  
17 distributor starts accumulating a very large  
18 inventory of controlled substances?

19 MS. YOCUM: Objection to form.

20 THE WITNESS: I think we were  
21 reaching out to them, so it was okay  
22 with us if they went ahead -- if we  
23 could ship this to them.

24 So, again, we are not the --  
25 the sole party in this stream of

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1 diversion and that as you referred to  
2 in -- before, you know, the  
3 distributors had their own programs in  
4 place for diversion.

5 As you can see from the e-mail,  
6 we were -- we were doing our part as  
7 far as checking why the order was  
8 placed, and in my view, we did our due  
9 diligence of reaching out to the  
10 business manager. The business  
11 manager had asked if -- on our behalf  
12 if they would take a larger increase  
13 of this product, and as far as I was  
14 concerned, that was okay for releasing  
15 the order.

16 QUESTIONS BY MR. KAWAMOTO:

17 Q. Do you know if Karen Harper  
18 signed off on the desire to have Cardinal  
19 increase their inventories?

20 A. I don't know that, no.

21 Q. Would this have been a decision  
22 she should have been involved in?

23 A. I'm not sure if she should be  
24 or not.

25 What's your -- what's your --

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1 well, okay. Go ahead.

2 Q. Well, would -- would you agree  
3 that it is a concern --

4 A. I can't -- I can't answer what  
5 Kate's thinking was on this or what was going  
6 on behind the scenes as far as us asking them  
7 to increase their inventories. Maybe they  
8 were keeping lower-than-expected inventories.  
9 Maybe -- I don't know. I can't answer for  
10 what reasons Kate Muhlenkamp had for asking  
11 for this.

12 Q. Well, I'm not asking for -- I'm  
13 not asking for your speculation as to what  
14 Kate was thinking.

15 A. Okay, but you're -- okay, go  
16 ahead.

17 Q. What I am asking is, from the  
18 standpoint of diversion control, is it a  
19 concern to have distributors accumulating  
20 large inventories of controlled substances?

21 A. If they have -- in my  
22 viewpoint, if they have the controls in  
23 place, it would not -- it would not be a  
24 problem.

25 Q. And by "controls in place,"

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1 what do you mean by that?  
 2 A. Suspicious order monitoring  
 3 program.  
 4 (Mallinckrodt-Rausch Exhibit 17  
 5 marked for identification.)  
 6 QUESTIONS BY MR. KAWAMOTO:  
 7 Q. So I'd like to mark this as  
 8 Exhibit 17.  
 9 A. Okay.  
 10 Q. So here's an e-mail from Cheryl  
 11 Nelson to Marc Montgomery and Kate  
 12 Muhlenkamp, and you're cc'd on it.  
 13 A. Correct.  
 14 Q. Do you recall receiving this?  
 15 A. No, but I see that I'm cc'd on  
 16 it, so I would have received it, I guess.  
 17 Q. Okay. And so Cheryl is asking  
 18 Kate and Marc about a shipment that has  
 19 triggered the -- the suspicious order  
 20 algorithm, or the peculiar order algorithm;  
 21 is that correct?  
 22 A. I don't know if it triggered  
 23 it, but from what I recall -- I don't know  
 24 where she's getting "we have experienced  
 25 considerable diversion tampering issues." I

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1 don't remember that, if that was the case  
 2 anymore.  
 3 But what they're saying here  
 4 is, there was a shortage, if I remember  
 5 right, of this product, and customers were  
 6 only allowed so much a month based upon  
 7 history, sales history, to them.  
 8 And from what I see here,  
 9 Cheryl was reaching out and asking who  
 10 were -- Kate and Marc, who were doing the  
 11 allocations, if it would be okay to ship them  
 12 material.  
 13 Q. Okay. And so Mark says that  
 14 it's okay, and Kate says that it's okay; is  
 15 that correct?  
 16 A. Okay. Yes.  
 17 Q. So would this order have been  
 18 shipped?  
 19 A. Yes, I would assume it would  
 20 be. I don't -- Kate -- yes, I would assume  
 21 it was, because it's not kicking out on the  
 22 suspicious order program.  
 23 Q. Okay. So no one did any  
 24 follow-up regarding what the considerable  
 25 diversion or tampering issues were with

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1 regard to this customer at NC?  
 2 A. I don't remember.  
 3 Q. Okay.  
 4 A. Again, I don't think it was  
 5 anything that kicked out as far as being on  
 6 a -- on the peculiar order report. I think  
 7 Cheryl was just reaching out and saying that  
 8 they had already reached the quantity of what  
 9 they could buy, and they were asking if they  
 10 could buy more or whatever. That's what I --  
 11 what I read out of this.  
 12 And she reached out to -- to  
 13 Marc Montgomery, who was the director of  
 14 marketing.  
 15 Q. So this -- and this would have  
 16 been sufficient to allow this shipment to go  
 17 through then?  
 18 A. Yes.  
 19 MR. KAWAMOTO: Okay. So why  
 20 don't we take a very short,  
 21 five-minute break, and I should be  
 22 close to wrapping up.  
 23 VIDEOGRAPHER: We're going off  
 24 the record at 5:06 p.m.  
 25 (Off the record at 5:06 p.m.)

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1 VIDEOGRAPHER: We are back on  
 2 the record at 5:14 p.m.  
 3 MR. KAWAMOTO: Okay.  
 4 Mr. Rausch, thank you for your time.  
 5 I have no further questions.  
 6 THE WITNESS: Okay. Thank you.  
 7 MR. TSAI: So just to clarify,  
 8 in case of redirect, I think I  
 9 probably have five minutes.  
 10 Do you want to do that now, or  
 11 should we do Tennessee first?  
 12 MS. CONWAY: I think  
 13 timing-wise, it should be fine for  
 14 her.  
 15 MR. TSAI: Okay.  
 16 VIDEOGRAPHER: We are going off  
 17 the record at 5:14 p.m.  
 18 (Off the record at 5:14 p.m.)  
 19 VIDEOGRAPHER: We are back on  
 20 the record at 5:15 p.m.  
 21 CROSS-EXAMINATION  
 22 QUESTIONS BY MS. HERZFELD:  
 23 Q. Mr. Rausch, how are you doing  
 24 this evening?  
 25 A. Getting tired.



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1 Q. Getting tired.  
 2 Okay. You're okay to go for  
 3 another hour or so?  
 4 A. Is that what it's going to be?  
 5 Q. Well, we'll see.  
 6 But do you feel like you're  
 7 okay, or do we need to reset this for  
 8 tomorrow?  
 9 A. No.  
 10 Q. Want to go forward now?  
 11 A. We can go forward.  
 12 Q. Okay. Great.  
 13 Well, my name is Tricia  
 14 Herzfeld, and I am one of the attorneys for  
 15 the plaintiffs in the Tennessee state  
 16 litigation known as the Staubus and Dunaway  
 17 cases in state court in Tennessee.  
 18 MS. HERZFELD: Before I start  
 19 with my questioning, I just wanted to  
 20 officially lodge an objection on  
 21 behalf of my clients that the  
 22 plaintiffs in the Staubus and the  
 23 Dunaway matter have not -- they've  
 24 been cross-noticed in this case but  
 25 have not been provided documents by

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1 Mallinckrodt in a timely way, nor in  
 2 compliance with the order issued out  
 3 of the MDL.  
 4 According to that order,  
 5 Mallinckrodt was required to produce  
 6 Mr. Rausch's complete and total  
 7 custodial file by November 2nd, 14  
 8 days in advance of this noticed  
 9 deposition. Mallinckrodt continued to  
 10 produce thousands of Mr. Rausch's  
 11 custodial documents after  
 12 November 2nd, finally concluding on  
 13 November 12, 2018, just a few days  
 14 before we came here today.  
 15 As required, 14 days before  
 16 this deposition Mallinckrodt stated  
 17 that Mr. Rausch had no  
 18 Tennessee-specific knowledge. The  
 19 Staubus and Dunaway plaintiffs aren't  
 20 sure if that is actually true, if you  
 21 have no knowledge about Tennessee  
 22 whatsoever, but we intend to ask you  
 23 questions about Tennessee, regardless.  
 24 By failing to abide by the  
 25 protocol, the plaintiffs in Staubus

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1 and Dunaway have been prejudiced in  
 2 their ability to prepare for this  
 3 deposition.  
 4 Additionally, the Tennessee  
 5 Drug Dealer Liability Act claims at  
 6 issue in the Tennessee litigation have  
 7 different elements and require  
 8 different discovery and areas of  
 9 inquiry than the MDL.  
 10 Also, the Tennessee Rules of  
 11 Civil Procedure do not place any time  
 12 restrictions on the length of  
 13 depositions. The Staubus and Dunaway  
 14 plaintiffs have requested two hours to  
 15 depose Mr. Rausch today, in addition  
 16 to the MDL's deposition time. We  
 17 requested it nine days before this  
 18 scheduled deposition, and we're happy  
 19 that we could work that out with the  
 20 parties.  
 21 But regardless, if for some  
 22 reason there are additional documents  
 23 that come forward at a later date, we  
 24 would be moving to redepose Mr. Rausch  
 25 at that time based on the violations

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1 I've just stated.  
 2 I'm sure you've got something  
 3 you'd like to say.  
 4 MR. TSAI: Yeah. For the  
 5 record, Mallinckrodt's position is  
 6 quite different from counsel's  
 7 recitation, and we reserve our rights  
 8 accordingly.  
 9 MS. HERZFELD: Great.  
 10 MR. TSAI: You can go ahead.  
 11 QUESTIONS BY MS. HERZFELD:  
 12 Q. Okay. Mr. Rausch, have you  
 13 ever been to Tennessee?  
 14 A. No, I have not.  
 15 Q. Okay. You haven't been for  
 16 pleasure or for work?  
 17 A. I drove through Nashville to go  
 18 to Florida.  
 19 Q. Okay. Did you stop?  
 20 A. No.  
 21 Q. Okay. Do you know when that  
 22 was?  
 23 A. No, not offhand.  
 24 Q. Since you retired?  
 25 A. Before I retired.

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1 Q. Okay. Okay. And do you have  
2 any friends or family that live in Tennessee?  
3 A. No.  
4 Q. Okay. And when you left  
5 Mallinckrodt, did you have any stock options  
6 with Mallinckrodt?  
7 A. No.  
8 Q. Okay. Have you ever owned any  
9 stock in Mallinckrodt?  
10 A. Years ago, but they've all been  
11 cashed.  
12 Q. Okay. And was that part of a  
13 compensation package for you?  
14 A. It was -- it was part of a  
15 management program.  
16 Q. Okay.  
17 A. The stock options were given at  
18 a particular price. They had nothing to do  
19 with sales or anything like that.  
20 Q. Okay. And what year was that?  
21 A. Oh, gosh. This is before  
22 probably 2000.  
23 Q. Okay. And was it just a  
24 one-time thing, or was it kind of year after  
25 year?

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1 A. It was for three or four years,  
2 and then they raised the level that they  
3 would give stock options, and I was no longer  
4 in the program.  
5 Q. Okay. When you say "they  
6 raised the level" --  
7 A. Of participation, as far as it  
8 went from managers up to director level, I  
9 believe.  
10 Q. And you were at what level?  
11 A. Manager.  
12 Q. And so they took managers out  
13 of the availability?  
14 A. Correct.  
15 Q. Okay. And how much would you  
16 say your stock options were worth when you  
17 cashed them in?  
18 A. I don't remember anymore.  
19 Q. Like 10,000? Hundred thousand?  
20 A. Some of them weren't worth  
21 anything because the stock dropped.  
22 Q. Okay.  
23 A. No less than -- probably less  
24 [REDACTED] but I'm  
25 guessing there.

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1 Q. Okay.  
2 A. I didn't go out and buy a new  
3 house or anything.  
4 Q. So you think roughly less than  
5 \$ [REDACTED]  
6 A. Correct.  
7 Q. Okay. Great.  
8 Okay. Would you agree with the  
9 statement that the opioid crisis seems to be  
10 worse in some areas of the country?  
11 MR. TSAI: Object to the form.  
12 THE WITNESS: Would I agree to  
13 that? I don't have that information.  
14 QUESTIONS BY MS. HERZFELD:  
15 Q. Okay. You said before that you  
16 did know -- have some knowledge about the  
17 opioid crisis in this country.  
18 A. From the news, yes.  
19 Q. Okay. And do you have any  
20 information about particular regions where  
21 the opioid crisis may be worse?  
22 A. No, I haven't really followed  
23 it since I've been retired.  
24 Q. You haven't followed the opioid  
25 crisis news at all since you've been retired?

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1 A. Well, I've followed it. I've  
2 seen it on the news, but it didn't talk  
3 specifically about areas that were of greater  
4 concern than others.  
5 Q. Okay. Have you read any books  
6 about the opioid crisis?  
7 A. No.  
8 Q. Okay. Have you heard  
9 particularly that the opioid crisis is  
10 particularly bad in Appalachia?  
11 A. No, I have not.  
12 Q. Okay. What about West  
13 Virginia?  
14 A. No.  
15 Q. What about Kentucky?  
16 A. No.  
17 Q. Virginia?  
18 A. No.  
19 Q. How about Tennessee?  
20 A. No.  
21 Q. You've never heard anything  
22 about the opioid crisis in Tennessee?  
23 A. Not that I remember.  
24 Q. Okay. What about Florida? Do  
25 you know anything about there being an opioid

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1 crisis in Florida?

2 A. Back in the -- when I was still  
3 employed, there was some information about  
4 Florida. I remember some news about Florida  
5 being a place of concern for the DEA, yes.

6 Q. Okay. And do you know where  
7 you obtained that information?

8 A. From the news.

9 Q. Okay. Did you ever obtain that  
10 information through your employment with  
11 Mallinckrodt?

12 MR. TSAI: Objection to this  
13 line of questioning. It's not  
14 Tennessee-specific.

15 But go ahead.

16 THE WITNESS: Karen Harper, our  
17 DEA compliance officer, brought it up  
18 to our attention.

19 QUESTIONS BY MS. HERZFELD:

20 Q. Okay. And what information did  
21 she give you?

22 A. She just noted that the DEA had  
23 sent out a bullet that there was some issues  
24 in Florida.

25 Q. Okay. And do you know roughly

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1 what year that was?

2 A. I'd be guessing. I don't know.  
3 Probably -- I'd be guessing.

4 Q. The '80s? '90s?

5 A. Oh, 2000s.

6 Q. 2000s.

7 Okay. Do you think it was  
8 before or after 2010?

9 A. Probably before.

10 Q. Okay. And did you make any  
11 changes based on -- to your job and your job  
12 duties based on that information that you  
13 received from Karen Harper about Florida?

14 A. Well, I believe, as you can see  
15 from the documents that we were reviewing or  
16 from what we talked about, that there was a  
17 growing concern from the DEA about diversion,  
18 and that's part of the reason why we enhanced  
19 our -- our program that we had in place,  
20 suspicious order program.

21 Q. Okay. And so you believe that  
22 the change in your suspicious order program  
23 was because of this information about  
24 Florida?

25 MR. TSAI: Object to the form.

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1 THE WITNESS: Well, no, I  
2 didn't say that.

3 QUESTIONS BY MS. HERZFELD:

4 Q. Oh, okay. I want to make sure  
5 I understand what you're saying, so correct  
6 me.

7 A. Yes. As I said, it was because  
8 the DEA was saying that there was increased  
9 diversion, and they were asking us to enhance  
10 our programs.

11 Q. Okay. So when the DEA was  
12 saying there was increased diversion, the way  
13 you took that was decreased diversion all  
14 over the country, but you knew specifically  
15 about issues in Florida?

16 A. Yes, there was bullets put out  
17 by the DEA to our DEA compliance people, and  
18 they passed on information about that.

19 Q. Okay. So you received specific  
20 information about Florida?

21 A. From what I remember, yes.

22 Q. Do you remember any other  
23 states?

24 A. I don't.

25 Q. Okay. Were you aware that

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1 people were traveling from other states to  
2 Florida for the purpose of obtaining opioids?

3 A. I was.

4 Q. And how did you become aware of  
5 that?

6 MR. TSAI: Objection. Vague as  
7 to time.

8 Go ahead.

9 THE WITNESS: Through what I  
10 was just talking about, information  
11 that Karen passed on to us.

12 QUESTIONS BY MS. HERZFELD:

13 Q. Okay. Did you know that people  
14 from Tennessee specifically were going to  
15 Florida to get opioids?

16 MR. TSAI: Objection. Vague as  
17 to time.

18 THE WITNESS: No, not  
19 specifically.

20 QUESTIONS BY MS. HERZFELD:

21 Q. Since 2000, that people were  
22 going from Tennessee to Florida to get  
23 opioids, were you aware of that?

24 A. Was there a question there?

25 Q. Yes.

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1 Were you aware of that?

2 A. No.

3 Q. Okay. Did the suspicious order

4 monitoring team monitor Tennessee news

5 articles?

6 A. No.

7 Q. Okay. Did the suspicious order

8 monitoring team monitor social media within

9 Tennessee?

10 A. No.

11 Q. Okay. Did the suspicious order

12 monitoring team review Tennessee disciplinary

13 actions of pharmacists and prescribers?

14 A. Not that I'm aware of.

15 Q. Okay. Did the suspicious order

16 monitoring team review third-party data for

17 red flags of diversion in Tennessee?

18 A. I don't know what the

19 compliance group was monitoring.

20 Q. Okay. And that would have been

21 done through the compliance group?

22 A. Correct.

23 Q. Did you ever review IMS Health

24 data or any other data to determine

25 suspicious orders in Tennessee?

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1 A. No, I did not.

2 Q. Okay. Would that have been

3 within your purview or that would have been

4 the compliance department?

5 A. That would have been

6 compliance.

7 Q. Okay. Did the suspicious order

8 monitoring team discuss red flags that could

9 indicate diversion in Tennessee with you or,

10 to your knowledge, to your team?

11 A. Say that again.

12 Q. Did the suspicious order

13 monitoring team discuss red flags that could

14 have indicated diversion in Tennessee with

15 you, or was there a discussion amongst the

16 team?

17 A. No.

18 Q. Okay.

19 A. Not that I remember.

20 Q. Okay. Did the suspicious order

21 monitoring team receive reports about

22 possible abuse or diversion of Mallinckrodt

23 opioids by distributors that supplied to

24 Tennessee?

25 MR. TSAI: Objection. Vague as

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1 to time.

2 THE WITNESS: Not that I

3 remember.

4 QUESTIONS BY MS. HERZFELD:

5 Q. Okay. I'm going to ask you

6 that question from 2000 to 2010.

7 Did you receive any reports

8 about distributors distributing to Tennessee

9 with issues of abuse and diversion?

10 A. I personally did not.

11 Q. Okay. And what about from 2010

12 until the time that you retired?

13 A. I personally did not.

14 Q. Okay. Did you ever hear of

15 either of those things?

16 A. No.

17 Q. Okay. Do you know if anybody

18 in your team would have knowledge if it

19 wasn't you?

20 A. I can't speak for them.

21 Q. Okay. Whose responsibility

22 would it to -- to have that information,

23 reports about suspected abuse and diversion

24 of distributors --

25 A. I believe if there was such

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1 reports, it would be going to our Karen

2 Harper in compliance.

3 Q. Okay. And would you have been

4 copied on those, or is that information you

5 should have had?

6 A. Would I have been copied? No,

7 not that I can remember.

8 Was it -- how it would affect

9 my job, I don't think so.

10 Q. Okay. What would have been

11 your role?

12 A. My role?

13 Q. Yes, sir.

14 A. In the suspicious order

15 monitoring program?

16 Q. If you had information that a

17 supplier that supplied to Tennessee was

18 having issues with abuse and diversion, you

19 would have a role in that, would you not?

20 A. Well, only an aspect if they

21 were -- they were placing orders with us that

22 would hit our suspicious order monitoring

23 program, that would have been my role.

24 Q. Okay. So I guess that's my

25 question.



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1 A. Okay.  
 2 Q. So I'm going to back it up  
 3 because maybe you didn't understand it.  
 4 A. Okay.  
 5 Q. So to your knowledge, you never  
 6 had any orders that came through that were  
 7 dinged as suspicious orders through your  
 8 suspicious order monitoring team from  
 9 Tennessee or from suppliers that supplied  
 10 pharmacies in Tennessee?  
 11 A. No.  
 12 Q. Okay. Who would know that?  
 13 A. To my knowledge, we did not  
 14 have any suspicious orders.  
 15 Q. Okay. So you would be the  
 16 person who would know that?  
 17 A. For that period of time, from  
 18 2009 to 2010.  
 19 Q. Okay. Okay. And after that,  
 20 it would have been?  
 21 A. I don't remember her name  
 22 anymore. I had the first name. It was in my  
 23 notes. I don't -- I'm getting a little -- I  
 24 don't remember her name. She was in the --  
 25 the rebate group.

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1 Q. Okay. So after you left that  
 2 position, she'd be the one who would know  
 3 that?  
 4 A. Right.  
 5 MR. TSAI: Objection.  
 6 Duplicative.  
 7 MS. HERZFELD: Can't be  
 8 duplicative if he doesn't know the  
 9 name.  
 10 MR. TSAI: No, this question  
 11 was asked before.  
 12 QUESTIONS BY MS. HERZFELD:  
 13 Q. Okay. On -- do you know if  
 14 Mallinckrodt's customer service department  
 15 had a relationship with any pharmacies in  
 16 Tennessee?  
 17 A. I do not know that.  
 18 Q. Okay. Do you know if any  
 19 Mallinckrodt employees ever detailed any  
 20 Tennessee pharmacies?  
 21 A. Detailed?  
 22 Q. Went and met with them, like a  
 23 sales call.  
 24 A. I don't -- I don't have  
 25 knowledge of that.

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1 Q. Okay. What about any detailing  
 2 of any Tennessee physicians by anyone at  
 3 Mallinckrodt, do you have any knowledge of  
 4 that?  
 5 A. No, I do not.  
 6 Q. Okay. Were you ever present  
 7 when opioid abuse or diversion issues in  
 8 Tennessee were discussed by any other  
 9 Mallinckrodt employee?  
 10 A. No.  
 11 Q. Have you ever seen any memos or  
 12 paperwork or any sort of a record talking  
 13 about --  
 14 A. Not that I can remember.  
 15 Q. -- abuse and diversion in  
 16 Tennessee?  
 17 A. No.  
 18 Q. Okay. Do you know if anyone on  
 19 the suspicious order monitoring team, while  
 20 you were involved with it, ever discussed any  
 21 problems with abuse or diversion with law  
 22 enforcement or other officials in Tennessee?  
 23 A. No, I do not remember that.  
 24 Q. Okay. Do you know which  
 25 distributors at Mallinckrodt did business

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1 with that shipped Mallinckrodt opioids to  
 2 Tennessee?  
 3 A. Which distributors we shipped  
 4 to in Tennessee?  
 5 Q. Yes, sir.  
 6 A. I don't recall that, who they  
 7 were.  
 8 Q. Okay. What types of records  
 9 would show who those were, the distributors  
 10 that shipped to Tennessee?  
 11 A. Order processing records.  
 12 Q. Okay. Anything else?  
 13 A. That would probably -- from my  
 14 point of view where I came from, order  
 15 processing would be one of the places that  
 16 records would be kept.  
 17 Q. Okay. Can you think of any  
 18 other spots, or is that the only one you can  
 19 think of?  
 20 A. That's the only one I can think  
 21 of.  
 22 Q. Okay. Did the suspicious order  
 23 monitoring team ever break down how many  
 24 particular pills were being shipped to a  
 25 state, on a kind of state-by-state basis?

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1 Did you ever look at that in the aggregate?  
 2 A. By state by state?  
 3 Q. Yes, sir.  
 4 A. Not that I'm aware of.  
 5 Q. Okay. Or by ZIP code or by  
 6 city?  
 7 A. No.  
 8 Q. Okay. Do you know what  
 9 percentage of Mallinckrodt opioids were sent  
 10 to Tennessee?  
 11 A. I do not.  
 12 Q. Okay. Do you know if there was  
 13 ever a consideration in the suspicious order  
 14 monitoring team about the number of opioids  
 15 shipped to a particular area compared to that  
 16 area's population?  
 17 A. No.  
 18 Q. Okay. So other than we talked  
 19 about Florida a little bit just a few minutes  
 20 ago, you said that the changes were  
 21 generally -- I'm paraphrasing you, so tell me  
 22 if I'm saying it incorrectly -- that the DEA  
 23 generally had some concerns about diversion  
 24 generally, and you knew specifically about  
 25 this issue in Florida.

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1 A. Correct.  
 2 Q. Based on that information, did  
 3 you treat Florida any differently than any  
 4 other state in performing your job  
 5 responsibilities?  
 6 A. Not my job responsibilities.  
 7 Our -- our reports from -- would --  
 8 nationally for all that would -- would take a  
 9 look at orders that were being processed from  
 10 Florida, like any other order, and kick out  
 11 peculiar orders from them.  
 12 Q. Okay. So I want --  
 13 A. At that time, yeah.  
 14 Q. I want to make sure I  
 15 understand your answer correctly.  
 16 So Florida would have been  
 17 looked at the same as any other state at that  
 18 point?  
 19 A. From what I remember.  
 20 Q. Okay.  
 21 A. There may have been -- you  
 22 know, we had a compliance group led by Karen  
 23 Harper that would visit distributors and  
 24 that. That may have been one of the areas  
 25 that they keyed in on. I'm not sure, but

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1 that would be a possibility.  
 2 Q. Okay. But to your knowledge,  
 3 from your perspective, everything was the  
 4 same?  
 5 A. From my perspective, correct.  
 6 Q. Okay. And so that would go for  
 7 Tennessee as well. Tennessee was never  
 8 treated differently than any other state?  
 9 A. Correct.  
 10 Q. Okay. Did you ever have any  
 11 discussion with any distributors about  
 12 problem prescribers in Tennessee?  
 13 A. No.  
 14 Q. Did you ever hear a discussion  
 15 of problem prescribers in Tennessee?  
 16 A. No.  
 17 Q. Okay. And what about problem  
 18 pharmacies?  
 19 A. No.  
 20 Q. Okay. Do you know if any  
 21 distributor orders going to Tennessee ever  
 22 appeared to be in your peculiar order report  
 23 or suspicious order report?  
 24 A. I don't remember. I don't  
 25 remember.

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1 Q. Is it possible to determine in  
 2 the aggregate, year by year, how many of  
 3 those suspicious orders or peculiar order  
 4 reports were generated for Tennessee? From  
 5 Tennessee?  
 6 A. Is it possible to do that? I  
 7 guess it's possible. I don't know how it  
 8 would be done, but I can't answer it any  
 9 further than that.  
 10 Q. When you put the information  
 11 into the computer or database or whatever --  
 12 A. Right. And looking at how far  
 13 back you're talking about, whether the data  
 14 is still available, someone from -- from IS  
 15 or whatever would have to put together a  
 16 report, if they could, of the history of  
 17 orders that were placed by companies in  
 18 Tennessee.  
 19 Q. Okay. And do you know what the  
 20 name of that database was or if there was --  
 21 A. JD Edwards.  
 22 Q. JD Edwards?  
 23 A. That was the order processing  
 24 system.  
 25 Q. Okay. And that's what was used

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1 at the time?

2 A. Yes.

3 Q. Okay. And do you have a

4 designation for state or region or something

5 geographically?

6 A. Yes.

7 Q. Okay. Great.

8 Do you know if there were any

9 Tennessee pharmacies on Mallinckrodt's

10 chargeback restriction list?

11 A. I'm not familiar with the

12 chargeback system.

13 Q. Okay. Do you know if anyone

14 from your team ever communicated with any

15 Tennessee pharmacies?

16 A. No.

17 Q. Did you ever communicate with

18 any Tennessee pharmacies?

19 A. Not that I -- no.

20 Q. Okay. And I'm not -- I may

21 have asked you this question, so if I did, I

22 apologize.

23 You don't recall any suspicious

24 orders coming from Tennessee for diversion or

25 overordering or anything?

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1 A. No.

2 Q. Okay. Do you have any

3 familiarity with Sunrise Wholesale?

4 A. I've heard of them.

5 Q. In Delray Beach, Florida?

6 A. Yes.

7 Q. Okay. Did you have any

8 involvement with Sunrise Wholesale while you

9 were at Mallinckrodt?

10 A. As far as what?

11 Q. Any discussions about them?

12 Meetings?

13 A. I remember Sunrise being

14 discussed. What was discussed, I don't

15 remember.

16 Q. Okay. Do you recall Tennessee

17 being mentioned in relation to Sunrise?

18 A. No.

19 Q. Okay. Do you know if Sunrise

20 Wholesale had been flagged for suspicious

21 orders or peculiar orders?

22 A. I don't remember.

23 Q. Okay. Did you ever learn at

24 some point that Sunrise Wholesale was being

25 investigated by the DEA?

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1 A. I don't remember.

2 Q. Okay. Did you ever attend any

3 meetings about the DEA investigation of

4 Sunrise Wholesale?

5 A. No, I didn't.

6 Q. Okay. Did you hear about a

7 sting operation in 2009 of -- in Tennessee

8 relating to Sunrise Wholesale in Florida?

9 A. No, I didn't.

10 Q. Okay. Have you ever spoken or

11 do you know a person named Pete Kleissle?

12 A. Doesn't ring a bell.

13 Q. Okay. DEA agent?

14 A. No, doesn't -- sorry.

15 Q. That's okay.

16 Have you ever spoken to a DEA

17 agent, to your knowledge?

18 A. Not that I can remember.

19 Q. Okay.

20 A. It was -- most of our

21 communication with the DEA was through Karen

22 Harper's group.

23 Q. Okay.

24 A. Our compliance group, I should

25 say.

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1 Q. Okay. Have you ever heard of

2 Dr. Barry Schultz?

3 A. Does not ring a bell.

4 Q. Okay. And do you know who

5 would have been involved in a decision to

6 continue to ship to Sunrise Wholesale after

7 July of 2009?

8 A. Who would have been involved?

9 Q. Who would have made that

10 decision.

11 Would that have been you?

12 A. Whether we were going to -- no,

13 that was above my pay grade.

14 Q. Okay.

15 A. It would have been our DEA

16 compliance group. They would have informed

17 us that we were no longer going to ship to

18 them.

19 Q. Okay. And if they didn't, you

20 would just continue shipping to them if

21 they're an existing customer?

22 MR. TSAI: Object to the form.

23 THE WITNESS: That's -- that's

24 asking me to -- I don't -- I'll answer

25 that by saying I don't think we do,

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1 because the compliance group would  
 2 have informed us not to ship to them  
 3 anymore.  
 4 QUESTIONS BY MS. HERZFELD:  
 5 Q. If there was already a raid?  
 6 A. Yes.  
 7 Q. Okay. But you don't have any  
 8 knowledge specifically about --  
 9 A. No, I don't.  
 10 Q. -- Sunrise?  
 11 Okay. Do you know who Steve  
 12 Becker is?  
 13 A. I do.  
 14 Q. Who is Steve Becker?  
 15 A. Steve Becker was a salesman.  
 16 Q. Okay. A salesman at  
 17 Mallinckrodt?  
 18 A. Correct.  
 19 Q. Okay. Do you recall attending  
 20 a meeting with Steve Becker in July of 2010  
 21 to talk about the oxy situation?  
 22 A. I don't recall it.  
 23 Q. Have you ever been in a meeting  
 24 with Steve Becker that you've talked about  
 25 diversion or oxy or anything like that?

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1 A. I don't remember.  
 2 Q. Okay. Do you recall ever  
 3 discussing Tennessee with Steve Becker?  
 4 A. No.  
 5 Q. Okay. Do you know a  
 6 distributor named KeySource Medical, Inc.?  
 7 A. I remember the name.  
 8 Q. Okay. Do you remember anything  
 9 specific about them?  
 10 A. They were a customer at some  
 11 point.  
 12 Q. Okay. In Florida maybe?  
 13 A. I would be guessing that they  
 14 were in Florida.  
 15 Q. Okay. Do you know if you had  
 16 any interaction with KeySource Medical?  
 17 A. No.  
 18 Q. Okay. Do you know if that --  
 19 you ever heard anybody mention or read in any  
 20 documents any interactions between KeySource  
 21 Medical and Tennessee?  
 22 A. No.  
 23 Q. Okay. Have you ever been to  
 24 Cincinnati?  
 25 A. I have been to Cincinnati.

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1 Q. Did you ever go to Cincinnati  
 2 for a meeting to discuss suspicious order  
 3 monitoring?  
 4 A. I believe we did.  
 5 Q. Okay. When do you think that  
 6 was?  
 7 A. I don't remember. Probably  
 8 2009.  
 9 Q. Okay. And do you recall what  
 10 the purpose of the meeting was?  
 11 A. To discuss their suspicious  
 12 order program, look to observe their  
 13 facility.  
 14 Q. When you say "them," who do you  
 15 mean?  
 16 A. Oh, I'm sorry.  
 17 Q. That's okay.  
 18 A. I believe -- I believe Karen --  
 19 well, I think Karen Harper was involved, but  
 20 I don't remember for sure. I believe our  
 21 VP -- VP of sales was involved. She went  
 22 along. And also our director of marketing  
 23 was also involved.  
 24 But our purpose, I believe, at  
 25 the time was to see what monitoring they had

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1 in their system for suspicious orders, that  
 2 type of thing.  
 3 Q. And when you say "monitoring in  
 4 their system" --  
 5 A. What their suspicious order  
 6 program was, if they had one, and what  
 7 their -- because we were doing some due  
 8 diligence, as I mentioned earlier, that we  
 9 were trying to outreach to other companies  
 10 that we dealt with to see if we could help  
 11 them in developing suspicious order reporting  
 12 if they didn't have it already.  
 13 Q. And which company were you  
 14 visiting?  
 15 A. I don't remember the name.  
 16 Q. Okay. You just knew it was in  
 17 Cincinnati and there was a big group of  
 18 people?  
 19 A. Yes.  
 20 Q. Okay. Okay. And you didn't  
 21 attend a DEA meeting in 2011 in Arlington,  
 22 Virginia?  
 23 A. No.  
 24 Q. Okay. I'm assuming that  
 25 because you said you've never met a DEA



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1 agent.  
 2 A. Right.  
 3 Q. Okay. Do you know anything  
 4 about Masters Pharmaceutical?  
 5 A. I remember the name, yes.  
 6 Q. Okay. And did you interact at  
 7 all with Masters Pharmaceutical?  
 8 A. Were they in Cincinnati?  
 9 Q. I wish I could answer that  
 10 question for you. I can't.  
 11 A. I don't -- okay. Because I  
 12 couldn't remember what the name of the  
 13 company was in Cincinnati.  
 14 Q. I don't have that information.  
 15 A. Did I interact personally with  
 16 them?  
 17 Q. Yes.  
 18 A. No.  
 19 Q. Do you know if anyone from your  
 20 team did?  
 21 A. By "your team," do you mean  
 22 compliance people?  
 23 Q. Yes, sir.  
 24 A. I'm sure there was some  
 25 inter -- I believe so.

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1 Q. Okay. Do you recall them  
 2 having any particular issues with suspicious  
 3 or peculiar orders?  
 4 A. I don't remember.  
 5 Q. Okay. Do you remember anybody  
 6 particularly kind of being repeat customers  
 7 for issues for suspicious or peculiar orders?  
 8 A. We didn't have -- in the time  
 9 frame that I had, we didn't have any  
 10 suspicious orders.  
 11 Q. Okay. So you've -- as was  
 12 already discussed, you would track those down  
 13 and eventually the order would go through?  
 14 A. Right.  
 15 Q. Okay. What about the Harbor  
 16 Medical Group in Livonia, Michigan, do you  
 17 recall any interactions with them?  
 18 A. I remember the name.  
 19 Q. Okay. And do you remember  
 20 anything particularly about them?  
 21 A. As far as --  
 22 Q. Suspicious orders?  
 23 A. -- compliance, that type of  
 24 thing?  
 25 Q. Yes, sir.

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1 A. I remember discussions about  
 2 Harbor being reviewed -- reviewed by the DEA.  
 3 Q. Okay. Do you remember who was  
 4 having those discussions?  
 5 A. The DEA.  
 6 Q. Okay. And do you recall who  
 7 told you?  
 8 A. I believe that was probably  
 9 from Karen Harper.  
 10 Q. Okay. And did Ms. Harper or  
 11 anyone else ever mention Tennessee in  
 12 connection with the Harbor Medical Group?  
 13 A. Not that I remember.  
 14 MS. HERZFELD: Okay. I don't  
 15 think I have any further questions for  
 16 this witness at this time. Thank you.  
 17 VIDEOGRAPHER: We're going off  
 18 the record at 5:46 p.m.  
 19 (Off the record at 5:46 p.m.)  
 20 VIDEOGRAPHER: We are back on  
 21 the record at 5:47 p.m.  
 22 CROSS-EXAMINATION  
 23 QUESTIONS BY MR. TSAI:  
 24 Q. Mr. Rausch, do you recall your  
 25 testimony earlier today regarding Mr. Howard

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1 Davis?  
 2 A. I do.  
 3 Q. Have you ever met Howard Davis?  
 4 A. Not that I can recall.  
 5 Q. Have you ever spoken with  
 6 Howard Davis?  
 7 A. Not that I can recall.  
 8 Q. Do you know whether Howard  
 9 Davis had any experience as of November 2010  
 10 in regard to developing or implementing any  
 11 suspicious order monitoring program?  
 12 A. I do not know if he did or not.  
 13 Q. Could you pull up Exhibit 10?  
 14 A. (Witness complies.)  
 15 Q. And if I could refer you to  
 16 Section 5, entitled "Background  
 17 Documentation."  
 18 A. Okay.  
 19 Q. Is it your understanding that  
 20 this is Mr. Davis' personal recommendation as  
 21 to additional background documentation for  
 22 Mallinckrodt to request for its customers?  
 23 A. That's my understanding.  
 24 Q. Are Mallinckrodt's customers  
 25 individual pharmacies?

<p style="text-align: right;">Page 338</p> <p>1 A. No.</p> <p>2 Q. Are Mallinckrodt's customers</p> <p>3 patients or end users?</p> <p>4 A. No.</p> <p>5 Q. Are Mallinckrodt's customers</p> <p>6 physicians or other prescribers?</p> <p>7 A. No.</p> <p>8 Q. Are Mallinckrodt's customers</p> <p>9 distributors or other manufacturers?</p> <p>10 A. Yes.</p> <p>11 Q. If you could go back to</p> <p>12 Section 5, and do you see the bullet point --</p> <p>13 one of the background documentation items</p> <p>14 recommended by Mr. Davis as of November 2010</p> <p>15 in this memo is "Do they self-medicate?"</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Could Mallinckrodt ask a</p> <p>19 distributor whether it self-medicates?</p> <p>20 MR. KAWAMOTO: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: No.</p> <p>23 QUESTIONS BY MR. TSAI:</p> <p>24 Q. If you could go to the very</p> <p>25 next bullet point: "Are they treating family</p>	<p style="text-align: right;">Page 340</p> <p>1 MR. TSAI: No further</p> <p>2 questions.</p> <p>3 MR. KAWAMOTO: Okay. I believe</p> <p>4 I'm permitted to recross.</p> <p>5 MR. TSAI: Yes. It's a</p> <p>6 minute-for-minute for recross.</p> <p>7 MR. KAWAMOTO: I guess I have</p> <p>8 seven minutes or six minutes.</p> <p>9 REDIRECT EXAMINATION</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. So, Mr. Rausch, your</p> <p>12 counsel asked you a number of questions</p> <p>13 regarding Section 5 relating to the types of</p> <p>14 information that could be solicited; is that</p> <p>15 fair?</p> <p>16 A. That's correct.</p> <p>17 Q. Could this information have</p> <p>18 been solicited from a distributor's</p> <p>19 customers?</p> <p>20 A. From a distributor's customer?</p> <p>21 Q. Yes.</p> <p>22 A. I guess it could be.</p> <p>23 Q. So this is information that</p> <p>24 could be gathered on Mallinckrodt -- on the</p> <p>25 customers of Mallinckrodt's customer,</p>
<p style="text-align: right;">Page 339</p> <p>1 members?"</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Could Mallinckrodt ask one of</p> <p>5 its distributor customers whether it is</p> <p>6 treating family members?</p> <p>7 A. No.</p> <p>8 Q. Could Mallinckrodt, looking at</p> <p>9 the next bullet point, ask one of its</p> <p>10 distributor customers how many patients do</p> <p>11 they see daily?</p> <p>12 A. No.</p> <p>13 Q. Going to the next bullet point,</p> <p>14 recommended by Mr. Davis, could Mallinckrodt</p> <p>15 ask one of its distributor customers about</p> <p>16 the number of patients to whom they dispense</p> <p>17 controlled substances?</p> <p>18 A. No.</p> <p>19 Q. Do these recommendations even</p> <p>20 make sense for a manufacturer like</p> <p>21 Mallinckrodt?</p> <p>22 A. Not to me.</p> <p>23 Q. And do you agree with</p> <p>24 Mr. Davis' recommendations here?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 341</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And using the chargeback data,</p> <p>4 Mallinckrodt could -- Mallinckrodt had an</p> <p>5 understanding of who the distributor's</p> <p>6 customers were; is that correct?</p> <p>7 MR. TSAI: Object to the form.</p> <p>8 THE WITNESS: I don't know how</p> <p>9 the chargeback data worked. I was not</p> <p>10 familiar with that process.</p> <p>11 QUESTIONS BY MR. KAWAMOTO:</p> <p>12 Q. Is it your understanding that</p> <p>13 the chargeback data could be used to identify</p> <p>14 the end users?</p> <p>15 A. I believe so.</p> <p>16 Q. Okay.</p> <p>17 A. But to -- do they</p> <p>18 self-medicate? I don't think they could find</p> <p>19 that information out and some of the other</p> <p>20 questions here.</p> <p>21 MR. KAWAMOTO: Okay. No</p> <p>22 further questions.</p> <p>23 THE WITNESS: Okay.</p> <p>24 VIDEOGRAPHER: We're going off</p> <p>25 the record at 5:51 p.m.</p>

<p style="text-align: right;">Page 342</p> <p>1 (Deposition concluded at 5:51 p.m.)  2 -----  3  4  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 344</p> <p>1 INSTRUCTIONS TO WITNESS  2  3 Please read your deposition over  4 carefully and make any necessary corrections.  5 You should state the reason in the  6 appropriate space on the errata sheet for any  7 corrections that are made.  8 After doing so, please sign the  9 errata sheet and date it. You are signing  10 same subject to the changes you have noted on  11 the errata sheet, which will be attached to  12 your deposition.  13 It is imperative that you return  14 the original errata sheet to the deposing  15 attorney within thirty (30) days of receipt  16 of the deposition transcript by you. If you  17 fail to do so, the deposition transcript may  18 be deemed to be accurate and may be used in  19 court.  20  21  22  23  24  25</p>
<p style="text-align: right;">Page 343</p> <p>1 CERTIFICATE  2  3 I, CARRIE A. CAMPBELL, Registered  4 Diplomate Reporter, Certified Realtime  5 Reporter and Certified Shorthand Reporter, do  6 hereby certify that prior to the commencement  7 of the examination, James Rausch was duly  8 sworn by me to testify to the truth, the  9 whole truth and nothing but the truth.  10 I DO FURTHER CERTIFY that the  11 foregoing is a verbatim transcript of the  12 testimony as taken stenographically by and  13 before me at the time, place and on the date  14 hereinbefore set forth, to the best of my  15 ability.  16  17 I DO FURTHER CERTIFY that I am  18 neither a relative nor employee nor attorney  19 nor counsel of any of the parties to this  20 action, and that I am neither a relative nor  21 employee of such attorney or counsel, and  22 that I am not financially interested in the  23 action.  24  25 CARRIE A. CAMPBELL, _____  NCRA Registered Diplomate Reporter  Certified Realtime Reporter  Notary Public   Dated: November 23, 2018</p>	<p style="text-align: right;">Page 345</p> <p>1 ACKNOWLEDGMENT OF DEPONENT  2  3  4 I, _____, do  5 hereby certify that I have read the foregoing  6 pages and that the same is a correct  7 transcription of the answers given by me to  8 the questions therein propounded, except for  9 the corrections or changes in form or  10 substance, if any, noted in the attached  11 Errata Sheet.  12  13 _____  14 James Rausch DATE  15  16 Subscribed and sworn to before me this  17 _____ day of _____, 20 _____.  18 My commission expires: _____  19 Notary Public  20  21  22  23  24  25</p>

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	ERRATA	
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